Author:
Hillard, Peter John

Title:
Aspects of the biomechanics of Ilizarov external fixation.

Aspects of the Biomechanics of Ilizarov External Fixation

Peter John Hillard

A dissertation submitted to the University of Bristol in accordance with the requirements of the degree of PhD in the Faculty of Engineering.

Department of Mechanical Engineering, March, 1999.

Abstract

The original Ilizarov frame is a form of circular external fixation in which bone fragments are supported by tensioned fine wires; the wires give the frame a non-linear axial stiffness which is one of its key qualities. However, as the wires deform plastically in response to loads imposed by functional weight bearing, the stiffness of frame gradually decreases with time. To circumvent this problem the modified Ilizarov frame was conceived in which half pins rather than wires are used for bone support. As fractures managed with Ilizarov fixation tend to unite with little radiographic evidence, monitoring the progression of fracture healing is difficult.

The study described in this dissertation had three primary objectives. The first was to investigate the significance of the plastic deformation which occurs in the tensioned fine wires to the long term performance of the original frame. The second was to investigate the biomechanics of the modified frame. The third objective was to conduct a *in-vivo* feasibility study on the use of fracture axial stiffness measurements as method of monitoring the progression of fracture healing.

Plastic deformation of the wires in the original frame readily occurs at moderate load levels because stress concentrations arise at the wire-clamp and wire-bone interfaces. The reduction in frame stiffness is typically 20-30%; re-tensioning only temporarily restores the original frame stiffness. In contrast to the original frame, the modified frame displays a linear stiffness and, as the half pins act as cantilevers, shearing of the bone ends can occur under axial loading. The *in-vivo* study showed that the technique of relative stiffness measurement, which has been successfully applied to uniaxial fixators, is not directly applicable to Ilizarov fixation. However, it was noted that the standard deviation of repeat measurements decreased with the progression of healing. It is suggested that this may arise as a result of decreased micromovement at the fracture site and might provide a means of monitoring fracture healing itself.

Acknowledgements

The author would like to express his sincere thanks to Dr. Andrew J. Harrison, Department of Mechanical Engineering, University of Bristol, and Mr. Roger M. Atkins, Department of Orthopaedic Surgery, Bristol Royal Infirmary, for their advice and guidance.

At the Bristol Royal Infirmary, the author would also like to thank the Physiotherapy Department, for their help and the use of their facilities, and Mr. Mark Jackson, Department of Orthopaedic Surgery, for allowing some of his patients to be included in the *in-vivo* study.

At the Department of Mechanical Engineering, the author would like to thank Mr. Fred Silk, and the other technicians, for their help and advice.

Finally, thanks are due to the patients who took part in the *in-vivo* study.

Author's Declaration

I declare that the work in this dissertation was carried out in accordance with the Regulations of the University of Bristol. The work is original except where indicated by special reference in the text and no part of the dissertation has been submitted for any other degree.

Any views expressed in the dissertation are those of the author and in no way represent those of the University of Bristol.

The dissertation has not been presented to any other University for examination either in the United Kingdom or overseas.

SIGNED: Peter Hillman DATE: 17/4/99

List of Contents

Abstract i
Acknowledgements ii
Author's declaration iii
List of Contents iv
List of Figures vii
List of Tables xiii

1. Introduction 1

2. Fractures and Fracture Management 5
  2.1 The Nature of Bone 5
  2.2 Fractures in Bone 8
  2.3 Fracture Fixation 12
  2.4 External Fixation of Fractures 15
    2.4.1 Advantages of External Fixation 17
    2.4.2 Disadvantages of External Fixation 19
  2.5 The Ilizarov Method 21
    2.5.1 The Ilizarov External Circular Frame 24
  2.6 The Assessment of Fracture Healing 26
    2.6.1 Fractures Managed with External Fixation 27

3. Biomechanics of the Ilizarov Frame 33
  3.1 The Original Ilizarov Frame 33
    3.1.1 Mechanical Testing of Fine Wires 35
    3.1.2 Finite Element Models 37
    3.1.3 Mechanical Testing 41
    3.1.4 Results 41

3.1.5 Discussion 47

3.1.6 Titanium wires 50

3.2 The Modified Ilizarov Frame 51

3.2.1 Finite Element Models 52

3.2.2 Results and Discussion 56

3.2.3 Shear Displacement in Response to an Axial Load 60

3.3 The Hybrid Ilizarov Frame 66

4. Mechanical Monitoring of Fracture Healing 67

4.1 Previous Studies 67

4.2 Axial and Bending Stiffness as Indicators of Fracture Healing 71

4.3 Absolute Stiffness Measurement 77

4.3.1 *In-vitro* tests 81

4.4 Relative Stiffness Measurement 84

4.4.1 The "Maggiore della Carità" Extensometer 85

4.4.2 Instrumentaion 90

4.4.3 *In-vitro* tests 94

4.5 Discussion 97

5. *In-vivo* Study of Relative Stiffness Measurement 99

5.1 Patients and Ethical Considerations 99

5.2 Test Protocol 102

5.3 Results and Discussion 106

5.4 Implications of the Results and Suggestions for Further Work 121

6. Conclusions 124

6.1 Summary of Research Findings 124

6.2 Recommendations for Further Work 128

References 130

Glossary 141

Appendix I - Patient Case Histories 143

Appendix II - List of the Author's Publications 155

Appendix III - Copy of Publication 14 158

List of Figures

1 A section of an original Ilizarov frame consisting of two rings, to each of which are attached two transfixion wires intersecting at 90°. 1

2 The structure of cortical bone. 6

3 Common patterns of fracture in long bones: a) transverse, b) oblique, c) spiral, and, d) comminuted. 9

4 Principal stages of secondary healing of cortical bone. 10

5 Methods of internal fixation: a) plate and screws or nails, b) cortical bone graft and screws, c) intramedullary nail with distal and proximal locking screws, d) oblique transfixion screws and e) circumferential wire bands.. 13

6 Types of external fixation: a) one plane unilateral frame incorporating half pins, b) one plane bilateral frame incorporating full pins, c) two plane circular frame incorporating wires, and d) multiplane circular frame incorporating half pins. ... 17

7 Principle stages in the treatment of a segmental defect caused by traumatic bone loss: a) comminuted fracture in which large sections of bone die due to disruption of the vascular structures, b) dead bone removed and fragment ends resected, c) corticotmy made with maintenance of integrity osteogenic tissue, *i.e.* periosteum, endosteum, and marrow, followed by gradual distraction of newly formed segment, and d) distraction stopped when regenerate length equals that of bone loss, primary union of bone ends follows. 23

8 Radiograph of patient T6 showing that frame components can obscure areas of interest on the radiographs. 28

9 Radiographs of patient T2; a) the day after frame application and, b) the day after frame removal 52 weeks later. Abundant callus material can be seen on the latter radiograph; particularly noticeable is the buttress indicated by the arrow. 29

10 Radiographs of patient F1; a) 2 weeks after frame application and, b) the day after frame removal, 18 weeks later. The fracture has united with the formation of little callus material; the small areas of callus material present are indicated by the arrows. 30

11 Rig for mechanical testing of wires. 36

12 Complete stress/ strain curve for one of the steel wires tested. 36

13 Yield point versus loading cycle for the steel wires tested. 37

14 Schematic showing the three principle stages in the execution of the models: a) section of wire, of length *L/2* - δ_x, was modelled with one end restrained, b) a displacement of δ_x was applied to the free end to produce the required level of pre-tension, and c) a displacement of δ_y, equivalent to that which would be caused by a load of 200 N was applied. 40

15 The relationship between the magnitude of a load applied perpendicular to the midpoint of a tensioned wire and the stiffness displayed by the wire over a single load cycle. Wire diameter, ring diameter and pre-tension were 1.8 mm, 180 mm and 981 N respectively. 42

16 The effect of wire diameter on the relationship between load and displacement over a single load cycle; ring diameter and pre-tension are 180 mm and 981 N respectively for all three wires. 44

17 The effect of wire length (ring diameter) on the relationship between load and displacement over a single load cycle; wire diameter and pre-tension are 1.8 mm and 981 N respectively for all three wires. 44

18 The effect of wire pre-tension on the relationship between load and displacement over a single load cycle; wire and ring diameter are 1.8 mm and 180 mm respectively for all three wires. 44

19 The effect of wire diameter on the relationship between tension and displacement over a single load cycle; ring diameter and pre-tension are 180 mm and 981 N respectively for all three wires. 45

20 The effect of wire length (ring diameter) on the relationship between tension and displacement over a single load cycle; wire diameter and pre-tension are 1.8 mm and 981 N respectively for all three wires. 45

21 The effect of wire pre-tension on the relationship between tension and displacement over a single load cycle; wire and ring diameter are 1.8 mm and 180 mm respectively for all three wires 45

22 Residual tension versus cycle of loading: a) for the hypothetical case where no work hardening occurs, and b) for the hypothetical case where the yield point assumes its maximum value after a single cycle of loading. The actual value of residual tension after a particular load cycle is contained in the envelope formed by these curves. 47

23 Complete stress/ strain curve for one of the titanium wires 51

24 Model 4: a) mesh plot, and b) deformed mesh plot. 55

25 Axial stiffness v. axial load for a range frame configurations: a) incorporating 6 rings, 12 pins, and between 1 and 6 connecting rods, b) incorporating 6 rings, 3 rods, and between 6 and 12 half pins and, c) incorporating 3 rods, and between 1 and 3 rings, each with two pins attached. 57

26 Deformed mesh plots of a of model 4: a) full frame for reference and, b) detail of the region surrounding the fracture gap in a plane bisecting the angle between the pairs of pins 61

27 Shear displacement of the bone ends versus axial load for model 15 (1 ring section) and model 4 (3 ring section) 63

28 Photograph of the frame applied to the left tibia of patient T6 65

29 Anterior-posterior radiograph of patient T6 31 weeks after frame application. A buttress of new bone in the posterior-lateral quadrant is indicated by the arrow. 65

30 The triphasic relationship between fracture tensile strength and the progression of healing, abscissa not to scale. After Prat *et al.* (109). 71

31 Fracture stiffness measurement: a) fracture model as a cylinder of callus/regenerate of length, L, and diameter, d, and, b) an applied moment, M, produces an angular deflection of θ. 73

32 Tensile stiffness measurement: configuration of instrumentation for the force bolt method. 80

33 Tensile stiffness measurement: configuration of instrumentation for the force washer method. 80

34 Instrument configuration for proving ring calibration. 82

35 Test rig for the absolute stiffness measuring technique: a) side elevation and, b) plan. Connecting rods and pin clamps have been omitted from the drawing for clarity. 83

36 Detail of the strain-gauged section of the "Maggiore della Carità" extensometer. 87

37 The pin deflection transducer, a) and, dimensions of the clamps and sensing elements, b). Not to scale. 91

38 The pin deflection transducer *in-situ* on a hybrid Ilizarov frame. 92

39 The instrumented connecting rod, indicated by an arrow, attached to a hybrid Ilizarov frame by means of a pair of 3-hole ranchos and pin clamps. 94

40 Mean strain measured by the instrumented connecting rod versus spindle mass; the graph shows the mean value and range over ten tests. 96

41 Connecting rod strain versus time for a patient with a fracture of the neck of the humerus managed with a uniaxial fixator. Data from Kristiansen and Borgwardt (57). A curve of the form $y = a + be^{-kx}$ has been fitted to the data by the present author. 106

42 Axial strain versus time for: a) to i), patients T1 to T9 and, j), patient F1. The mean and range of the 10 measurements taken at each test session are shown.... 111

43 Standard deviation of axial strain versus time for: a) to i), patients T1 to T9 and, j), patient F1. 10 measurements were taken at each test session. 115

List of Tables

1 Chemical composition of ASTM F138 grade 2 stainless steel wire for surgical implants (91). 35

2 Results of tensile tests on a sample of 12 steel wires. 36

3 Mean yield points (in MPa) for a sample of 12 steel wires subjected to multiple load cycles 37

4 Frame configurations modelled. 39

5 Residual displacement of the model 1 configuration determined by mechanical testing. 41

6 Residual displacement and tension for the seven models after a single loading cycle of 200 N. 43

7 Total residual displacement for the two models subjected to multiple cycles of loading. 46

8 Results of tensile tests on a sample of 12 titanium wires. 50

9 Modified frame configurations modelled. 53

10 Estimated axial compression stiffness for a range of frame configurations. Ring, pin and rod diameters are 180 mm, 6 mm, and 6 mm respectively in all cases. Ring spacing has been ignored. 56

11 Comparison of experimental and calculated values of the axial compression stiffness of a frame consisting of 4 rings of 180 mm diameter and 8 half pins of 6 mm diameter. 60

12 Mean mechanical properties of fractures in healing rat femora expressed as ratios of the mean properties of healed fractures. Data from Walsh, W.R. *et al.* **(112)**. 77

13 Comparison of values of proving ring stiffness values and mean values of ten measurements made by the force bolt and force washer methods. 84

14 A comparison of theoretical strain and mean strain, over ten tests, measured with the instrumented connecting rod. 96

15 *In-vivo* study of relative stiffness measurement: Patient data. 100

16 Injury severity classification. After Richardson *et al.* **(52)**. 100

17 Coefficients of the curves fitted to the datasets of patients T1 to T9, and F1. The curves had the general form $s = a + be^{-kt}$. 115

CHAPTER 1. Introduction

During the early 1950s the technique of distraction osteogenesis was pioneered by Gavril Ilizarov working at the Kurgan All-Union Centre for Restorative Traumatology and Orthopaedics, in the former Soviet Union. Distraction osteogenesis is a technique for treating segmental defects in bone by the formation of new sections of bone and provides a technique for treating a range of conditions which were previously untreatable such as congenital limb-length inequalities. To provide the appropriate biomechanical environment for distraction osteogenesis to take place, Ilizarov developed the form of circular external fixation which now bears his name, figure 1.

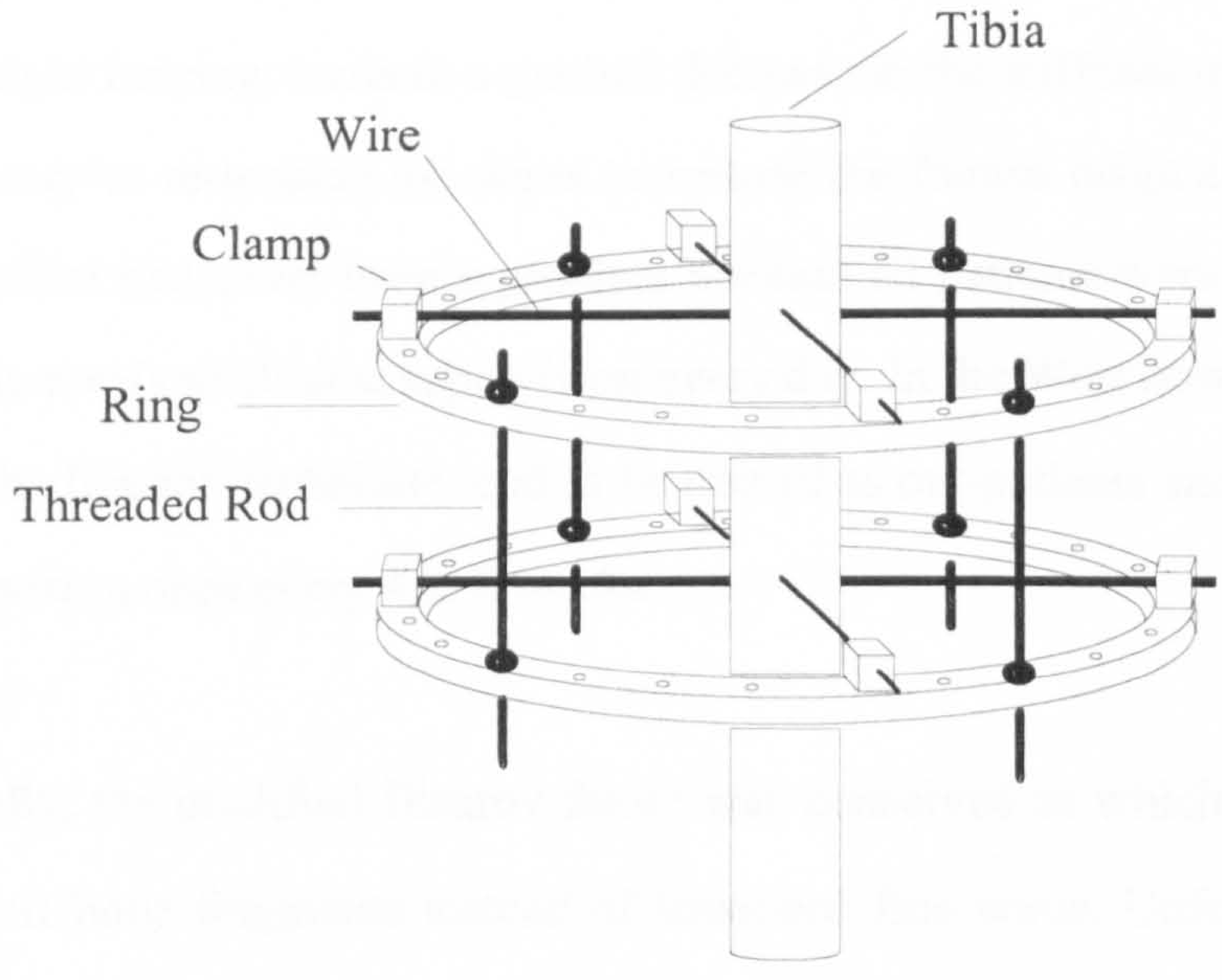


Figure 1 A section of an original Ilizarov frame consisting of two rings, to each of which are attached two transfixion wires intersecting at 90°.

The original Ilizarov frame consisted of steel rings connected together with steel rods to form an exoskeleton around the limb. The exoskeleton is connected to the bone by a series of tensioned fine wires inserted through the bone, and surrounding soft tissues, and held by clamps at either end which are attached to the rings. The tensioned fine wires give the frame a non-linear axial stiffness which is one of its key qualities. In response to loads imposed by functional weight bearing, the frame allows low amplitude cyclical axial motion, which is beneficial to fracture healing because it stimulates vascularisation but, inhibits high amplitude axial motion which is deleterious to the healing outcome.

Following its introduction to the West in the late 1980s, the Ilizarov frame began to be used to treat less serious conditions because of its greater geometric versatility over other forms of external fixation. However, a number of drawbacks of the original Ilizarov device became apparent. Of these, one of the most serious is that progressive plastic deformation of the wires, in response to loads imposed by functional weight bearing, leads to a gradual decrease in the stiffness of the frame; it is then necessary to re-tension the wires to restore the frames original stiffness. At Kurgan this effect had never been a problem because all patients were treated as in-patients and so received clinical supervision every day. In the West however, patients treated with the Ilizarov technique tend to be treated as out-patients and only receive clinical supervision once every 4 to 6 weeks.

Consequentially, the modified Ilizarov frame was conceived in which half pins are used to support bone fragments instead of tensioned fine wires. Unfortunately, the modified Ilizarov frame does not share the non-linear axial stiffness of the original Ilizarov device. Additionally, the motion of the bone ends in response to an axial load usually has a shear, as well as an axial component, because the half pins act as cantilevers. By contrast, in the original device motion of the bone ends in response to an axial load is generally purely axial. Therefore, the majority of frames currently used are of a hybrid type, in which both tensioned fine wires and half pins are present.

The most serious disadvantage of the Ilizarov system, however, is shared with most other forms of external fixation and is that conventional techniques of assessing fracture healing are inadequate under conditions of external fixation. Fracture union is conventionally assessed by a combination of the physical manipulation of the limb and radiography. Physical manipulation is obviously not possible with the frame *in-situ* and as fractures treated with external fixation tend to unite without presenting much radiographic evidence, radiography is equally impotent.

This dissertation describes 3 studies. One used a combination of finite element analysis and direct mechanical tests to assess the significance of the plastic deformation of the tensioned fine wires on the long-term performance of the original Ilizarov frame. The second investigated the relative contributions of individual frame components to the overall stiffness of the modified frame using finite element analysis. The third study was an investigation of techniques which might be used to monitor the progression of fracture healing by measuring the axial stiffness of the healing fracture. All 3 studies were carried out at the instigation of, and in collaboration with, surgeons at the Department of Orthopaedic Surgery at the Bristol Royal Infirmary.

Section 2 provides a general background for the rest of the dissertation and briefly covers the nature of bone, fractures in bone, the biologic process of fracture repair, the management of fractures, and the assessment of fracture healing. Section 3 describes the finite element studies of the original and modified Ilizarov frames; by way of a summary the probable biomechanics of the hybrid frame are also briefly discussed. In section 4 previous studies in which stiffness measurements have been used to monitor fracture healing are reviewed, and the relative merits of bending and axial stiffness as indicators of fracture healing and strength are considered. The development and *in-vitro* testing of methods for measuring the absolute axial stiffness and relative stiffness of healing fractures are also described.

Section 5 describes an *in-vivo* trial of one of the relative stiffness methods described in section 4. The 10 patients included in the trial were coded T1 to T9, and F1, where T indicated a tibial fracture and F a fracture of the femur; these patients are used to illustrate discussions in other parts of the dissertation. Conclusions from the three studies are given in section 6 and are followed by the list of references. Medical terms used in the text are generally defined on first usage but, to prevent excessive repetition, and to aid the reader, a small glossary of the most commonly used terms is included after the references. The case histories of the patients included in the *in-vivo* study are given in appendix I. A list of the author's publications are given in appendix II; and a copy of one is reproduced in appendix III. The work described in section 3 has been published in publications 2, 5, 8, and 14. Preliminary results from the study described in sections 4 and 5 have been published in publication 12.

CHAPTER 2. Fractures and Fracture Management

The following chapter provides a background for the rest of the thesis. The biology of bone, with particular reference to long bones, the nature of fractures in such bones and the biologic process of fracture repair are first described. Conventional methods of fracture management are then discussed and a group of conditions for which conventional techniques are non-viable is identified. With reference to this group of conditions, methods of external fixation are then discussed. The Ilizarov method for correcting segmental defects in bone, and the Ilizarov circular external frame are then described. The main deficiency of external fixation techniques, *i.e.* the lack of an adequate method of assessing the stability of a healing fracture with the frame *in-situ,* is then discussed. The investigation of suitable methods of assessing the stability of healing fractures under conditions of external fixation formed the primary objective of this project.

2.1 The Nature of Bone

Bone is composed of an organic matrix called osteoid which consists of collagen fibres embedded in a cementing gel of protein polysaccharide. On the surface of the fibres needle shaped crystals of calcium hydroxyapatite (CHA) are deposited. In the bone of adults the collagen fibres and CHA crystals are aligned parallel to the average stresses to which the bone is submitted. Bone stiffness, and strength, are dependent on both the normal formation of the osteoid and mineral, and on the alignment of the fibres and crystals.

The long bones of adults consist of tubes of cortical bone with an inner and outer sheath of tissue, called the endosteum and periosteum respectively; the hollow centre of the bone contains marrow and trabeculae, *i.e.* struts, of cancellous bone. The compact bone of the cortex consists of a series of fundamental units, called osteons, consisting of a central blood vessel, a group of cells called osteocytes, minute canaliculi connecting the osteocytes with the central blood vessel, and lamellae of collagen fibres/CHA crystals, figure 2. The osteocytes are of two types, osteoblasts which lay down new bone and osteoclasts which absorb bone; the processes are concurrent and continuous.

The periosteum consists of an outer layer containing many blood vessels and nerves, a middle fibrous layer, and an inner layer which contains latent osteocytes, *i.e.* osteocytes that can develop into either osteoclasts or osteoblasts as required. The endosteum also contains latent osteocytes. When a fracture occurs osteocytes from the endosteum and periosteum invade the fracture site and commence its repair. The main blood supply to the bone is via a nutrient artery which supplies the marrow, endosteum, and the inner two thirds of the cortex. The metaphyseal regions, *i.e.* the expanded ends of the bone, are supplied by separate blood vessels and the outer third of the cortex is supplied via blood vessels from the periosteum.

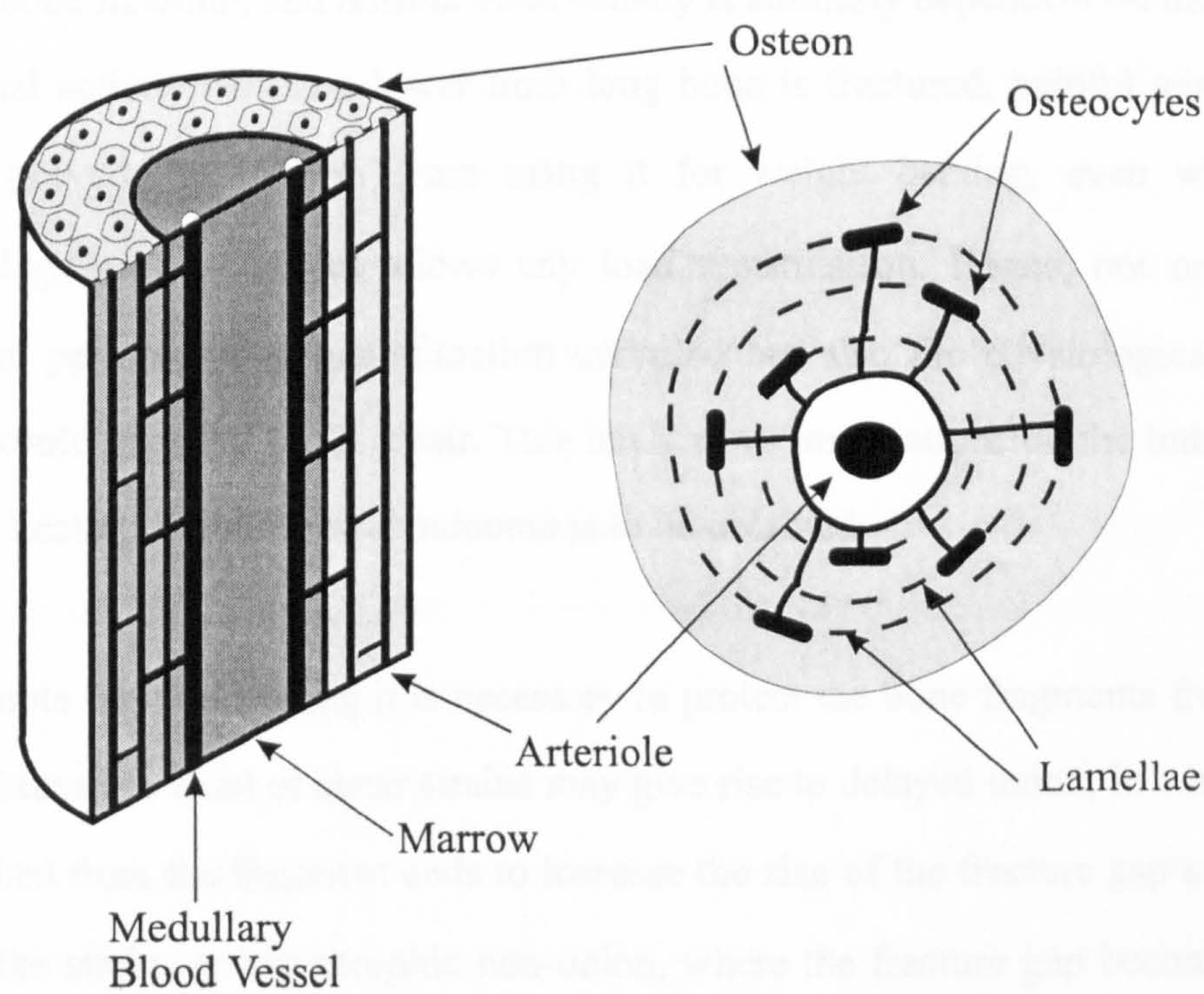


Figure 2 The structure of cortical bone.

The osteocytes in the osteons of living bone are continually active, breaking down and replacing bone in a process known as remodelling. Remodelling provides a repair mechanism for the wear and tear of minor trauma and protection against fatigue failure(1). It also permits realignment of lamellae, and changes in bone mass, in response to changes in the prevailing mechanical loads applied to the bone (2,3). Hence, the skeletons of babies can undergo rapid and considerable postnatal change (4); athletes can develop particularly strong bones for specialist purposes (5), etc. The obvious disadvantage of bone remodelling is that in areas relieved of usual stresses inappropriate alignment of the lamellae and a reduction of bone mass will occur (6,7). An extreme example of this is that astronauts who spend extended periods in reduced gravity environments are prone to develop osteoporosis (8).

Thus, mechanical loading provides a physiological influence which acts to maintain the mass and orientation of bone tissue appropriate for the structural demands made on it. Normal bone form will develop and be maintained only in the presence of normal bone function, and normal bone density is similarly dependent on the level of functional activity. When a lower limb long bone is fractured, painful stimuli will largely prevent the subject from using it for weight bearing, even where the morphology of the fracture allows any load transmission. Hence, not only is its ability to perform its normal function curtailed but also the physiological stimuli which would give rise to its repair. This has serious implications on the induction of fracture healing if a successful outcome is to be obtained.

To promote fracture healing it is necessary to protect the bone fragments from gross strain. Excessive axial or shear strains may give rise to delayed union, in which bone is resorbed from the fragment ends to increase the size of the fracture gap and hence reduce the strain, or hypertrophic non-union, where the fracture gap becomes filled with cartilage and fibrous tissue and a pseudarthrosis forms. However, if there is no strain at all in the fracture gap, slow union, *i.e.* excessively slow healing, or atrophic non-union, *i.e.* non-union due to the de-vitalisation of the bone ends, may occur (9-12).

2.2 Fractures in Bone

Fractures may be subdivided into three groups:

1) Pathological fractures - fractures through bone already weakened by disease such as osteoporosis. Often the bone gives way from trivial violence, or even spontaneously.

2) Fatigue fractures - occur when bones are subjected to excessive repeated stress and are generally confined to the bones of the feet in dancers, long-distance walkers and other such individuals.

3) Traumatic fractures - fractures caused solely by sudden injury are by far the most common. They may be caused by direct violence such as a sharp blow, or by indirect violence transmitted along the bone.

Fractures adopt patterns which are indicative of the nature of the causative mechanism and are, therefore, classified by these patterns. The patterns most common in long bones are: transverse fractures, oblique fractures, spiral fractures and comminuted fractures, figure 3. Spiral fractures are caused by torsional stresses and as bone is less able to withstand torsional than tangential stresses these fractures are usually 'low energy' fractures associated with a lesser degree of soft tissue and skin damage. Tangential stresses produce a transverse or oblique fracture; more severe violence results in a comminuted fracture, *i.e.* one with more than two fragments. Comminuted fractures are generally 'high energy' fractures and are associated with a greater degree of soft tissue and skin damage. Thus, a knowledge of the mechanism which gave rise to the fracture is important because it indicates the most suitable method of reduction and the likely extent of soft tissue damage. Together with the fracture pattern it determines the stability of the bone fragments and indicates the most suitable forms of fixation (**13,14**)

a) b) c) d)

Figure 3 Common patterns of fracture in long bones: a) transverse, b) oblique, c) spiral, and, d) comminuted.

The process of fracture healing involves the bridging of the defect by bony material, its subsequent remodelling to a strong union and reconstitution of the bone to something like its previous state. There are two main ways in which fracture healing can occur: primary and secondary healing. Primary healing occurs by the direct extension of osteogenesis from the bone ends into the fracture gap by a process similar to normal remodelling. It rarely occurs naturally and is associated with internal fixation and rigid external fixation where interfragmentary motion is effectively precluded. Primary healing progresses more slowly than secondary healing and is characterised by an absence of radiographically visible callus (**15**). In secondary, or spontaneous, healing the fracture is first stabilised by the formation of peri- and interfragmentary callus. Secondary healing of cortical bone may be considered as occurring in five stages, figure 4.

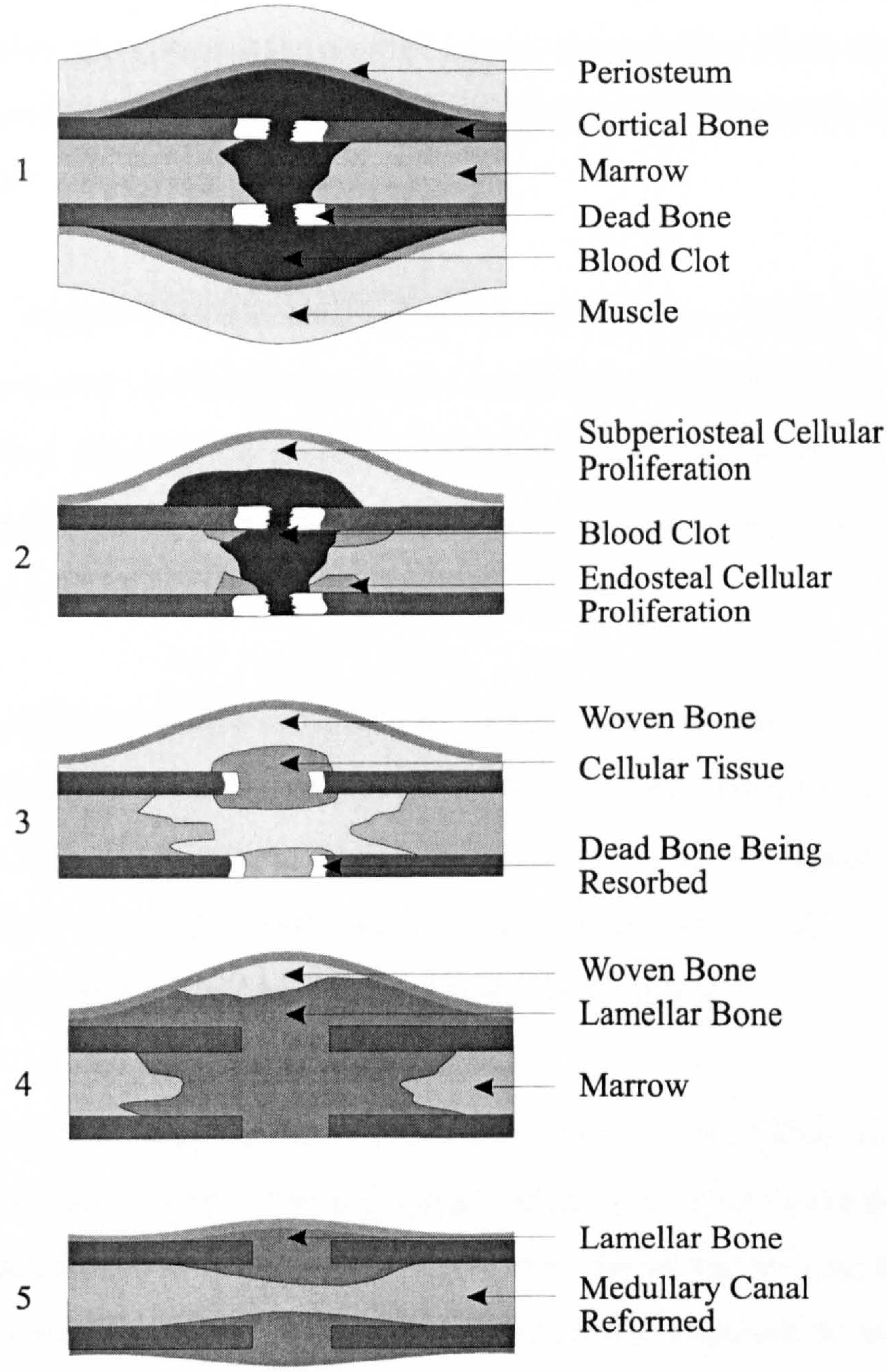


Figure 4 Principal stages of secondary healing of cortical bone.

1) Haematoma formation - As a result of fracture, bleeding occurs from the damaged bone ends and soft tissue, forming a haematoma, or blood clot. The fracture inevitably divides the capillaries running longitudinally through the cortex of the bone and may also damage the medullary blood vessels. Thus deprived of a blood supply, a certain amount of bone near the fracture site dies.

2) Subperiosteal and endosteal cellular proliferation - Capillaries from the periosteum and endosteum invade the clot and transform it to granulation tissue, they are followed by osteoblasts from the same sources. The osteoblasts form a collar of active tissue around each of the bone fragments which grows out towards the adjacent fragments.

3) Callus formation - The cellular proliferation raises the periosteum away from the bone cortex and the osteoblasts in it form a bridge of woven bone, *i.e.* bone in which the collagen fibres/CHA crystals are not aligned, called the callus. The callus imparts some stability to the fracture and is visible on radiographs giving an indication the fracture is uniting.

4) Callus consolidation - The woven bone of the callus is gradually transformed by the activity of the osteoblasts into more mature bone with a typical lamellar structure. When the callus material has matured the fracture is said to be 'clinically united' and the means employed to stabilise the fracture is removed. The final thickness of the callus is inversely proportional to the stability afforded the fracture during the callus formation/consolidation stages (16). Low fracture stability leads to the formation of a great deal of callus material, high fracture stability leads to the formation of very little. However, in the former case a bridge may fail to form.

5) Bone remodelling - Over a period of several months the bone is gradually strengthened along the lines of stress at the expense of the surplus bone outside the lines of stress, which is slowly removed. Thus the excess callus is gradually removed and the medullary canal reformed.

2.3 Fracture Fixation

The first stage in the treatment of a fracture of a long bone is reduction, i.e. the restoration of the bone fragments to their pre-fracture positions and alignments. There are several techniques for accomplishing the reduction of a fracture, *i.e.* manipulation, traction or as a last resort operative reduction, but as they are beyond the remit of the present study they will not be discussed here. However, it is worth noting that external fixation, and the Ilizarov technique in particular, allows for the reduction of complex fractures, for which manipulation and traction are unsuitable, in a manner which is considerably less disruptive to the surrounding tissues than open surgery.

The next stage of treatment is immobilisation, or fixation. There are three reasons for immobilising a fracture: to prevent displacement or angulation of the fragments, for relief of pain in order to restore some degree of functional utility, and to prevent movement that might interfere with union. Particularly deleterious to the healing outcome are shear motions between the bone fragments which promote the formation of fibrocartilage instead of bone in the fracture gap (**17**). Gross axial motions are also undesirable because they lead to bone being resorbed from the fracture ends to reduce the level of strain (**18, 19**).

However, as mentioned above, it is not necessarily desirable to prevent all movement at the fracture site. Several studies have shown that fracture healing can be promoted by induced cyclic compression, of controlled magnitude and frequency, at the fracture site (**20 - 23**); the same result has been shown for induced cyclic distraction (**24**). Other studies have shown that cyclic strain imposed on the fracture gap by functional weight bearing under conditions of semi-rigid fixation can have the same effect (**11, 12, 25-28**). Such motions stimulate vascularisation of the region and promote callus formation and consolidation.

The commonest method for immobilising a fracture is to enclose the limb in a plaster of Paris cast. The degree of stability provided by the cast is comparatively low compared to that provided by internal or external fixation and so the method is generally used for fractures where the danger of re-displacement is relatively low such as transverse fractures. Another limitation is that access to the soft tissues is precluded and so in cases were access is required, or there is a danger of excessive swelling, casts are not suitable. Continuous traction is another technique which is sometimes used to immobilise a fracture. However, it entails long-term in-patient treatment and so is expensive, and disruptive for the patient.

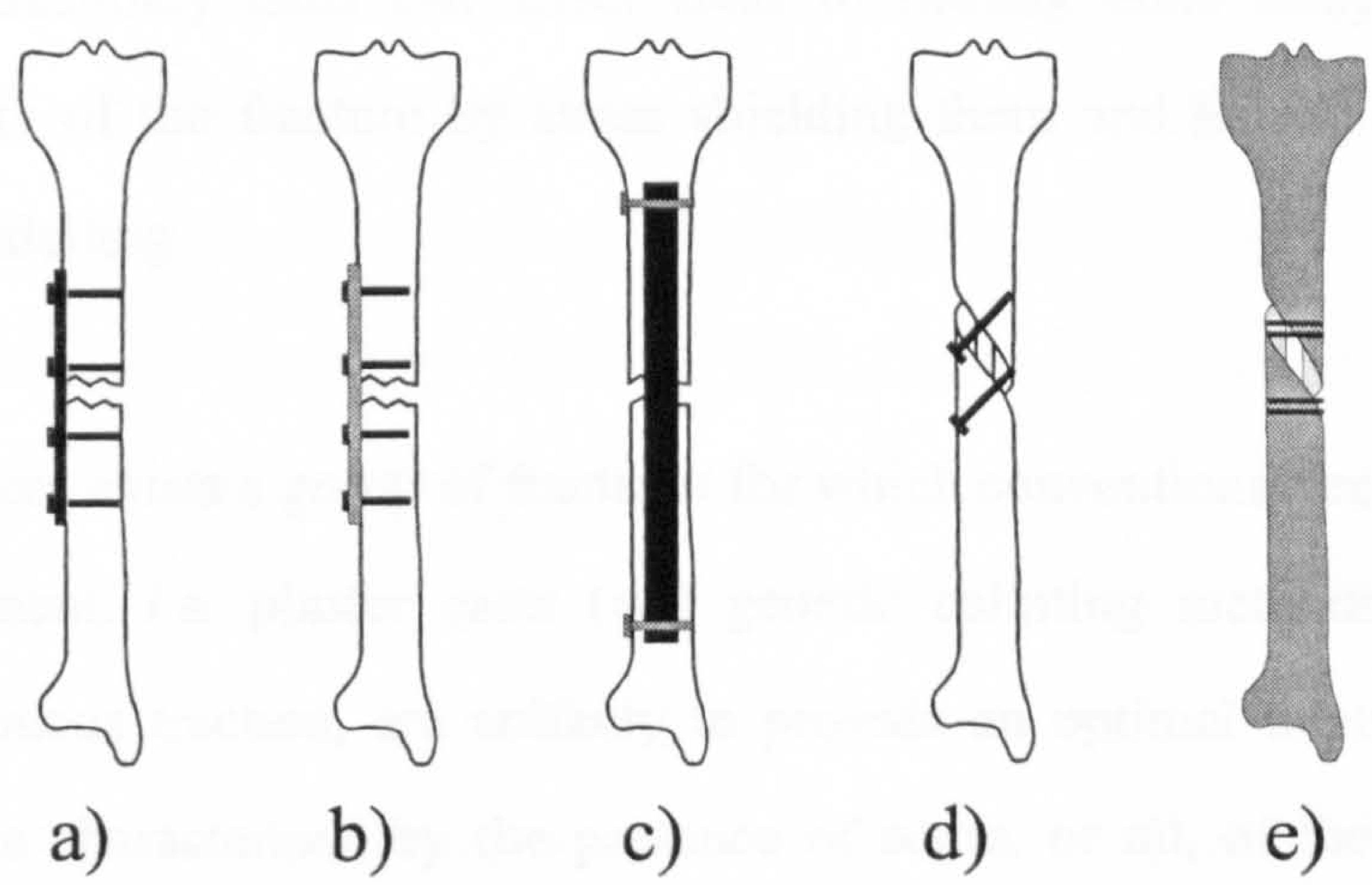


Figure 5 Methods of internal fixation: a) plate and screws or nails, b) cortical bone graft and screws, c) intramedullary nail with distal and proximal locking screws, d) oblique transfixion screws and e) circumferential wire bands

Where the danger of re-displacement is greater, and especially where operative reduction is required, a greater degree of stability can be obtained by use of internal fixation methods. Internal fixation involves the surgical introduction of an implant to stabilise the bone fragments until callus consolidation occurs; the implant is then removed to allow bone remodelling. Amongst the commonest implants used are: plates held by screws or nails, cortical bone grafts held by screws, transfixion screws, intramedullary nails, *i.e.* hollow cylinders inserted into the medullary canal, and circumferential wires or bands, figure 5.

The obvious disadvantage of such techniques is the disruption to the soft tissues by open surgery and the possible complications arising therefrom. Where the soft tissues suffered considerable damage at the time of fracture internal fixation is unlikely to be a viable treatment. One of the prerequisites for successful bone healing is an adequate blood supply; any disruption of the soft tissues reduces the blood flow to the region. Other problems can arise from the biocompatibility of the implants. Plates and intramedullary nails can affect areas of healthy bone away from the immediate vicinity of the fracture by stress shielding them and hence, interfering with normal remodelling.

To summarise, there exists a group of fractures for which conventional techniques of fracture management, *i.e.* plaster casts (and generic splinting methods), internal fixation or continuous traction, are unlikely to provide an optimal treatment (29). Such fractures are characterised by the presence of some, or all, of the following factors:

1) A fracture pattern requiring complex reduction

2) A degree of soft tissue damage making operative reduction non-viable

3) The presence of skin or soft tissue injuries requiring extended treatment

4) An unstable fracture pattern predisposed to re-displacement

External fixation provides an effective form of management for such fractures. It also has several other advantages that have increasing led to its use for the management of less severe injuries. It will be discussed in detail below.

2.4 External Fixation

External fixation is a method of stabilising fractures which employs pins which are attached to the bone at one end, pass through the surrounding soft tissues, and are fixed to a rigid external metal or composite frame. The earliest attempts to use such a system were made in the 1850s (30) but the rudimentary clinical hygiene of the day lead to severe problems in the form of pin-tract infections and the concept was not well accepted until the 1930s. The course of the subsequent development of the method was closely linked to major military conflicts such as World War II and the Vietnam war. Lower limb injuries inflicted by military armaments are characterised by highly comminuted fractures together with extensive disruption of the surrounding soft tissues. External fixation techniques provide particularly effective means of managing such fractures.

External frames vary greatly in appearance but are all composed of structural elements with analogous purposes, *viz.*:

- Elements interfacing with the bone fragments, e.g. pins, half pins and wires.
- Elements to provide longitudinal support, e.g. rods, articulated rods and extending rods.
- Elements to connect the two, e.g. clamps, universal joints and rings

Although an almost infinite number of frame configurations occur, all can be classified as belonging to one of two main groups, linear or circular. Linear frames can be further subdivided into unilateral and bilateral groups. In unilateral frames the elements interfacing with the bone are half pins; in bilateral frames, pins or wires are used which pass right through the bone and are connected to rest of the frame at either end; in circular frames either half pins, wires, or a combination of the two, may be present. An advantage of unilateral frames is that it is easier to avoid transfixing neurovascular structures in the soft tissues when inserting half pins. However, bilateral frames are stiffer in torsion and compression and have the advantage that axial loads produce a purely axial displacement of the bone ends. In contrast, half pins act as cantilevers and so the displacement of the bone fragments in response to an axial load usually has a shear component. Shearing of the bone ends can lead to non-union of the fracture.

External frames can be further subdivided by considering the number of planes in which it is possible to arrange the elements interfacing with the bones. Hence, simple unilateral and bilateral frames are one plane devices; if an extra plane is required it is necessary to add an extra unit (31, 32). Circular frames using wires are two plane devices while circular frames using half pins, or a mixture of wires and half pins, offer the possibility of multiple plane fixation, figure 6.

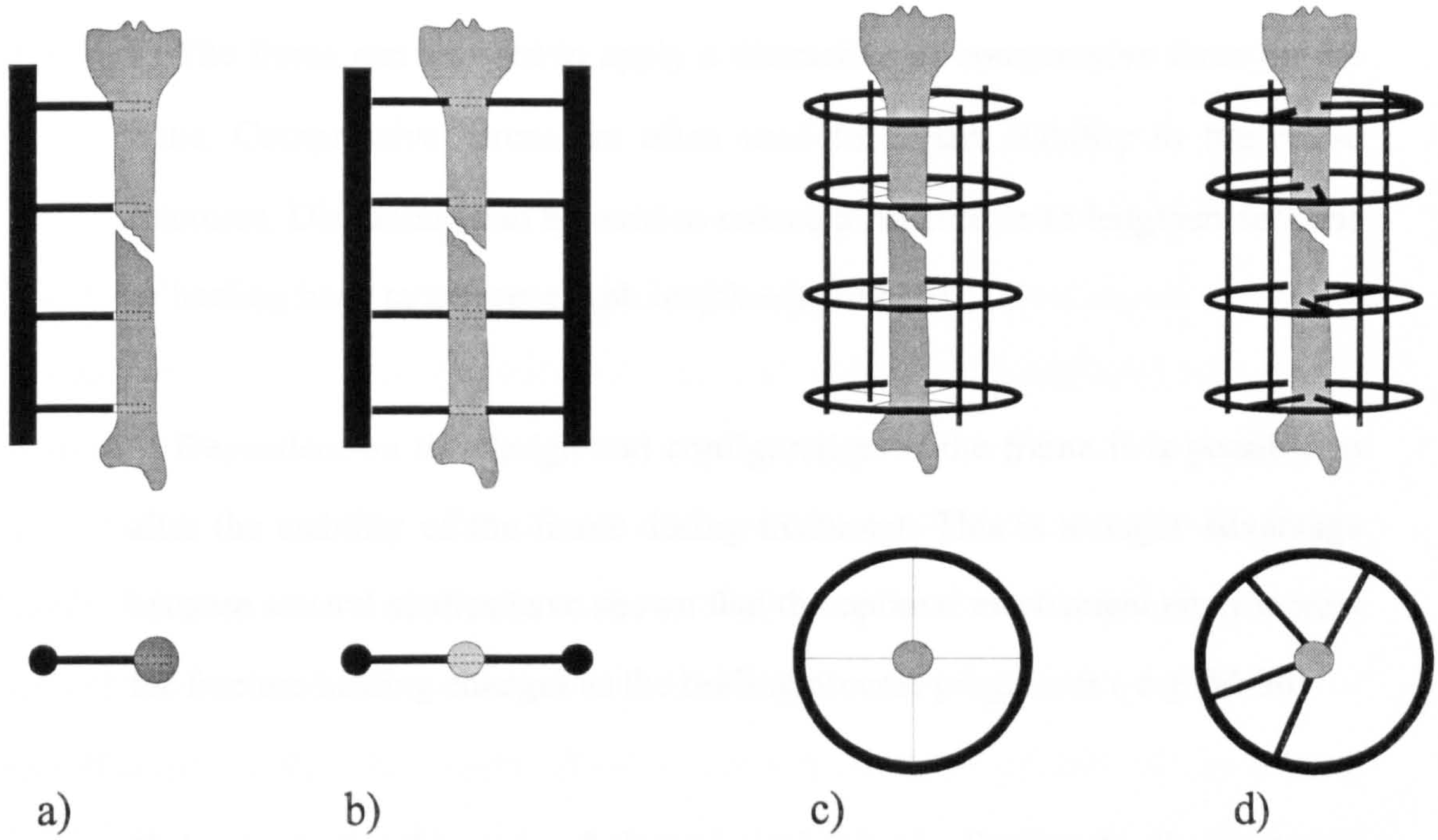


Figure 6 Types of external fixation: a) one plane unilateral frame incorporating half pins, b) one plane bilateral frame incorporating full pins, c) two plane circular frame incorporating wires, and d) multiplane circular frame incorporating half pins.

2.4.1 The Advantages of External Fixation

External fixation has numerous advantages over conventional techniques of fracture management, *viz.*:

1) External frames are adjustable and hence allow the surgeon to make alterations in the alignment, angulation or rotation of bone fragments during the first few weeks of healing without the need for further surgery. This can be very important where a complex reduction is required but extensive soft tissue damage precludes operative reduction.

2) The frame can be used to apply a distractive or compressive force on the bone. Compressive forces are often used to impart stability to transverse fractures. Distraction can be used to reduce a fracture or to lengthen sections of healing bone to preserve limb length equality (33).

3) Dependent on the design and configuration of the frame it is possible to alter the stability of the frame during treatment. This is a major advantage because several studies have shown that the optimal mechanical environment for fracture healing changes as the healing process progresses (e.g. 34-36)

4) Access to the skin and soft tissue is maintained, allowing for the treatment of skin burns, wounds, etc.

5) The frame can be rapidly and easily applied to fractures with minimal blood loss and disruption to the soft tissues. This is especially important in cases of polytrauma where fractures may be neglected in the early stages of treatment in favour of more serious injuries.

6) External frames provide for excellent pain relief and early mobility. In the case of tibial and femoral fractures, patients are often up within a few days and using the limb for functional weight bearing.

7) Joint mobility, though possibly impaired by some frame designs and configurations, is largely maintained. In contrast, where conventional casts are used it is necessary to immobilise the joints above and below the fracture which has significant implications on the final rehabilitation of the patient (29).

2.4.2 The Disadvantages of External Fixation

External fixation has numerous minor disadvantages such as the weight of the frames and their propensity to frighten patients. The former can be overcome by use of lighter materials, such as composites or titanium, and the latter through better patient education. The method also requires of the patient a greater degree of involvement in the treatment of his fracture than is the case of conventional techniques. Numerous small tasks, such as pin site cleansing, applying the distraction regime, etc., must be carried out several times a day if a successful outcome is to be obtained. Problems of compliance can therefore occur. Another problem is the high cost of the frames. However, many of the frame parts can be re-used for several subsequent patients and so represent a capital expenditure.

The minor problems discussed above are not insurmountable but there are three fundamental problems in the current state of the art of the technique: the possibility of pin tract infections occurring, the risk of the frame itself causing damage to bone and soft tissue, and the lack of a reliable method to assess the stability of a healing fracture with the frame *in-situ*. These will be briefly considered below.

> Pin tract infections develop if the pins and wires are not properly inserted and cared for. Apart from adding to patient morbidity, such infections can give rise to serious problems which jeopardise the successful outcome of the treatment. The infection can lead to ostoemyelitis and necrosis of the bone around the pin, or wire, holes. This loosens the pins and hence, reduces the stability of the frame. Even worse, the infection can give rise to a non-union. Where an infected non-union develops the ends of the bone fragments become dense and rounded, and the healing process comes to an end with no attempt to bridge the fracture gap. Surgical intervention is then necessary to remove the 'healed' bone ends and restart bone union. Some authors suggest

that infection occurring in the pin tracts is an inevitability and that the only way to mitigate its effects is to minimise the duration of treatment (29).

Damage can be caused to bone around the pin, or wire, holes if the latter are made to carry excessive loads. The damage can take the form of either direct fractures or more commonly pressure necrosis. In the latter case regions of bone subjected to excessive compressive stress die leading to loosening of the pins and the possible subsequent development of the problems outlined above. To avoid such problems the number or diameter of the pins can be increased but this can increase the risk to the soft tissues. Compression, distraction and bone transport, *i.e.* the transport of one or more bone fragments relative to the others, are commonly carried as part of the treatment. In all three cases the frame and at least some of the bone fragments move relative to the soft tissues and so the pins, or wires, connecting the frame and bone cut through the soft tissues. In the case of half pins, the extent of such damage can be reduced by inserting the pins at an acute angle to the direction of transport, but at the cost of frame stability (37).

The most serious deficiency with the current state of the art is the lack of an adequate means of assessing the stability of the healing fracture with a frame *in-situ*. A knowledge of the fracture's stability is required to verify that healing is progressing adequately in the early stages of treatment and to determine the time for frame removal. Premature removal of the frame is likely to end in re-fracture. Late removal of the frame increases the cost of treatment, has economic and personal consequences for the patient, increases the risk of pin tract infections and other complications, and may affect the viability of previously unaffected bone through stress shielding (38).

Conventionally, fracture stability is assessed by a combination of physical manipulation and radiographic evidence of the extent of callus formation. In the case of external fixation physical manipulation is not viable with the frame *in-situ*. Radiographic evidence is equally unsatisfactory because, as mentioned above, the extent of callus formation is inversely proportional to the stability of fracture fixation. Thus, the relatively high stability afforded the fracture by an external frame leads to the formation of little callus material; in some cases union occurs by primary bone healing and no callus material is seen (9). In the absence of a satisfactory means of assessing fracture stiffness, surgeons resort to leaving the frames in place for excessive periods to avoid re-fracture.

2.5 The Ilizarov Method

The Ilizarov method is a technique for growing segments of new bone *in-situ* to increase the length, or breadth, of a bone (39, 40). The method provides a technique for treating a wide range of conditions which were previously either, a) totally incurable or b) curable but only with shortening of the limb or other complications. These conditions fall into three categories:

1) Congenital disorders - e.g. limb length inequalities, dwarfism and angular, or rotary, deformities. Generally, such conditions were previously untreatable. In the case of dwarfism, the objective is not to give the patient normal stature, because the thorax cannot be lengthened, but to increase the patient's height enough to allow him/her to function in a normal environment, e.g. to reach light switches, etc. (41-43).

2) Bone loss - due to trauma, infection or tumour. These conditions were only treatable where bone loss, and subsequent limb shortening, was minor. Where

bone loss was excessive, the limb would have been amputated. A recent study has shown that the cost of limb salvage with the Ilizarov method is considerably lower than that of amputation when the cost of prostheses, etc., is taken into account (44).

3) Trauma residuals - there exists a range of conditions which can arise from the failure of a conventional technique of fracture management to produce a satisfactory healing outcome, a good example being non-union. Though alternative forms of treatment exist for these conditions they are often best treated with the Ilizarov method. In several centres the Ilizarov method is used exclusively for the treatment of such conditions. The method has several other uses like the lengthening of amputation stumps to improve prostheses fitting.

The Ilizarov method involves the division of the cortex with minimal disruption to the periosteum, endosteum, marrow and vascular structures. This can be achieved by passing a wire around the bone and then tensioning the wire to crack the cortex; the fracture thus created is then left latent for a couple of weeks until new bone forms in the gap. Then, one of the two bone segments is slowly distracted away from the other at a rate of 0.5 to 1.0 mm per day. The production of new bone continues until a length of regenerate is formed equivalent to that of the segmental defect at which time distraction is stopped. The newly formed regenerate is then allowed to consolidate. The initial formation of the regenerate is favoured by very stable fixation of the bone segments; unstable conditions lead to the formation of fibrocartilage rather than regenerate bone. The subsequent consolidation of the regenerate is favoured by less stable conditions(17, 45-47). The precise procedure varies considerably with the type of condition being treated, *i.e.* bone lengthening, a segmental defect with an associated fracture, etc., figure 7.

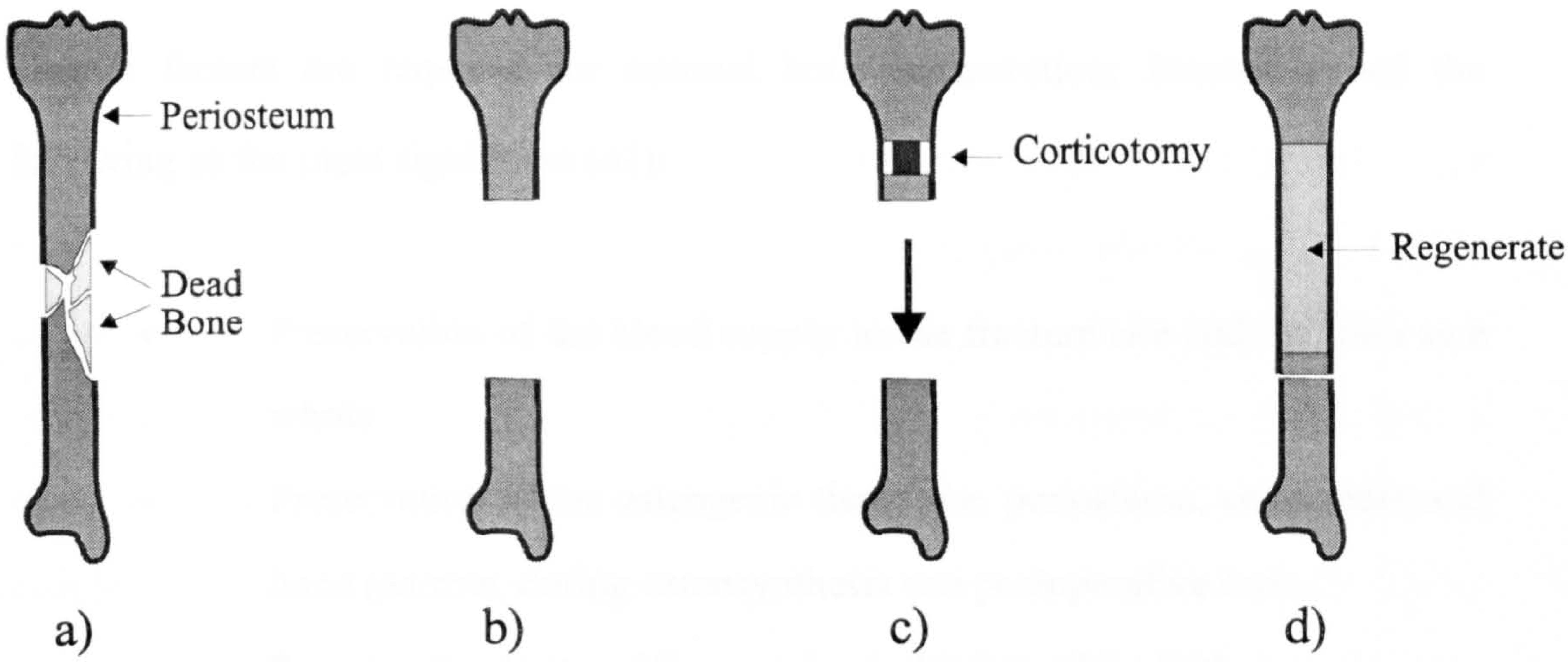


Figure 7 Principle stages in the treatment of a segmental defect caused by traumatic bone loss: a) comminuted fracture in which large sections of bone die due to disruption of the vascular structures, b) dead bone removed and fragment ends resected, c) corticotmy made with maintenance of integrity osteogenic tissue, *i.e.* periosteum, endosteum, and marrow, followed by gradual distraction of newly formed segment, and d) distraction stopped when regenerate length equals that of bone loss, primary union of bone ends follows.

The basis of the Ilizarov method is what its originator termed the 'tension-stress effect', *i.e.* that gradual controlled distraction stimulates new bone production. When a distractive force is applied to a healing fracture, the tissue fibres and cells orientate themselves in the direction of the applied force; this mimics the process of remodelling as described above.

Certain factors are required for optimal bone regeneration; Ilizarov stated the following as the most significant (41):

- Preservation of the blood supply to the fracture site and the limb as a whole
- Preservation of the osteogenic tissue, *i.e.* periosteum, endosteum and bone marrow, during osteosynthesis and postoperative care
- Functional activity of the muscles and joints of the limb
- Early patient mobilisation
- Precise reduction and firm fixation of the bone fragments

The successful fulfilment of the last three factors is dependent on the form of fixation used. The requirements to apply distraction, obtain early mobilisation, provide a high degree of stability at the fracture site, etc., preclude all methods other than external fixation. Of the available forms of external fixation, circular frames are by far the most versatile and capable of performing the tasks required by the Ilizarov method. They offer greater geometric versatility, potentially lower weight, the ability to carry out angular correction and the ability to accurately manipulate very small bone fragments in three dimensions. These advantages led Ilizarov to develop a type of circular external frame, generally referred to as the Ilizarov frame, for use with the method. The Ilizarov frame will be briefly discussed below.

2.5.1 The Ilizarov external circular frame

The original Ilizarov apparatus consists of steel rings connected together with steel rods to form an exoskeleton around the limb. The rings are available as full rings, or partial rings of various diameters and typically have about 40 holes to allow the attachment of connecting rods, wire clamps, etc. The connecting rods are available in various lengths and may be plain, threaded, or graduated telescopic rods. The exoskeleton is then connected to the bone by a series of wires inserted through the bone and soft tissues and held by clamps at either end which are attached to the rings, figure 1. The wires are generally arranged in pairs, ideally approximately perpendicular to each other, to prevent the bone sliding along them (48). Where it is not possible to insert the wires at 90° to each other, olive wires, *i.e.* wires with a small central bead may be used to prevent slipping. In addition to these basic components a range of special components are used to construct frame configurations for special purposes. These include: slotted and drilled plates, hinges, joints, universal joints, etc. Virtually every frame used has a unique configuration tailored to the condition to be treated.

After its introduction to the West from the former USSR, several deficiencies of the original Ilizarov apparatus became apparent. The frame was difficult to apply, and could be heavy and extremely painful for the patient, particularly where the fine wires transfix muscle groups and are used for bone transport. The difficulty experienced in applying the frame has been addressed by developing new surgical procedures and the use of segmental rings which can be assembled around the limb rather than threaded onto it. Segmental rings made from composite materials have been introduced which are radiolucent and much lighter than the steel ones, thus reducing the weight of the frame (49). The painful soft tissue transfixion by the fine wires has been reduced by the use of parallel wire constructs (50), or eliminated by the use of titanium half pins which are approximately equivalent in weight and are easier to insert into safe areas. It should be noted though, that these modifications have not been universally adopted and many centres use frames which are very similar to Ilizarov's original.

2.6 The Assessment of Fracture Healing

The conventional techniques for assessing fracture repair are plain radiography and physical manipulation to estimate the stiffness of the fracture. A range of other indicators is used for corroborative purposes. These include the presence, or absence, of tenderness at the fracture site on clinical examination, and the patient's own assessment of stability when weight bearing. Both plain radiography and the manual assessment of fracture stiffness have been shown to be unreliable; the limitations of both will be briefly considered below.

Manual assessment of fracture stiffness is inherently subjective as has been demonstrated by a recent study (51). In the study 40 subjects were asked to assess the stiffness of 7 fracture models with stiffnesses of 5, 7.5, 10, 12.5, 15, 20 and 65 Nm/degree. These values were chosen because a fracture stiffness of 15 Nm/degree measured biomechanically has been proposed as a reliable indicator of fracture union in the human tibia (52); 65 Nm/degree represented an intact tibia. The subjects consisted of: 10 orthopaedic consultants, 10 orthopaedic registrars, 10 medical students, and 10 engineers. The consultants greatly overestimated the stiffness of the fracture models, particularly those of lower stiffness. On 83 per cent of occasions when the stiffness was less than 15 Nm/degree, the surgeons considered the fracture united. All four groups had difficulty in correctly ranking the fracture models according to stiffness and the consultants and registrars were less accurate than the other groups. The authors concluded that these results suggested that the ability to estimate fracture bending stiffness accurately is not improved by experience. Given the small sample size such a conclusion is probably not justified, though the study does show the unreliability of the technique.

Another, more fundamental, limitation on the use of bending stiffness as a qualitative measure of fracture healing arises from the implicit assumption that a simple correlation exists between the bending stiffness and the strength of a healing fracture. A study using osteotomised sheep tibiae as a fracture model, found that during the initial stages of healing there was a strong correlation between bending stiffness and strength but that during later stages, including the period when clinical union occurred, no significant correlation existed between the two (53). This suggests that, whilst bending stiffness may be used to assess progress towards union, it is an unreliable indicator of fracture strength at the time of union.

The assessment of fracture healing using plain radiography is a subjective process which involves quantifying the amount of callus formation around the fracture site. The limitation of the technique arises from the fact that no direct correlation exists between the quantity of callus and the mechanical strength of the fracture (36, 54). Furthermore, whilst the formation of callus material implies that healing is progressing normally, it does not guarantee that it is. In several conditions, such as hypertrophic non-union, large volumes of callus material are produced but osseous union is not achieved and the strength of the fracture remains low (16). Finally, it is worth repeating that when union occurs through primary bone healing no callus material is visible on the radiographs. The only radiographic evidence that union has occurred is that the fracture line slowly disappears (15).

2.6.1 Fractures Managed with External Fixation

Further limitations are imposed on the techniques of plain radiography and physical manipulation when a fracture is managed with external fixation. Physical manipulation is not possible with the frame *in-situ*. In some linear frames which use pins to support the bone fragments it is possible to temporarily disconnect the pins from the supporting elements allowing manipulation, but this is not possible in circular frames. With radiography the obvious problem is that suitable radiographs may be difficult to obtain because of the radiopacity of the frame components, figure

8. However, a more serious problem occurs in rigid frames such as the Ilizarov device. Whilst some fractures heal by the secondary mode, figure 9, many heal by a process similar to primary healing with little callus formation, figure 10. In these cases plain radiography is of little use as a technique for assessing the quality of fracture union.

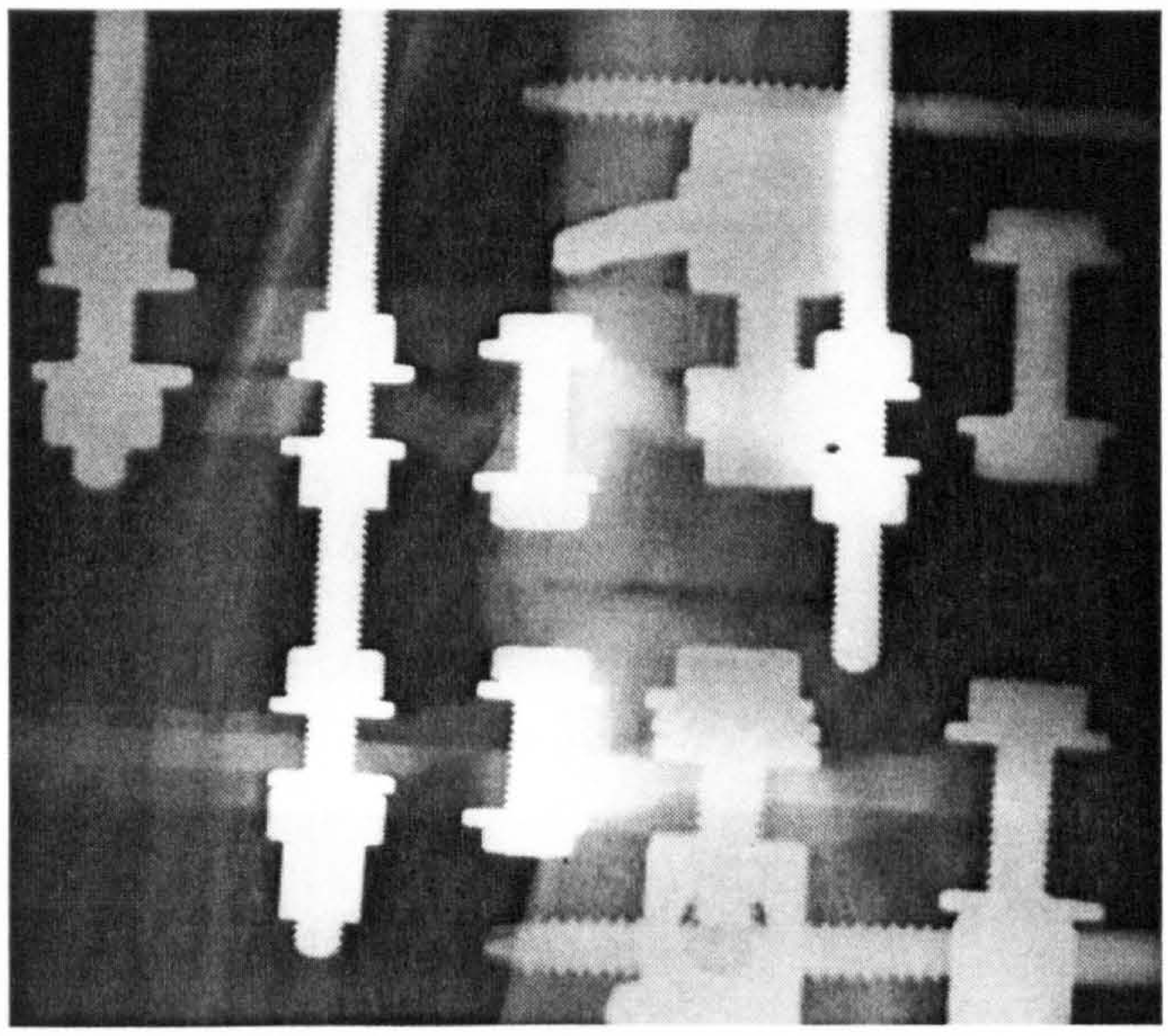
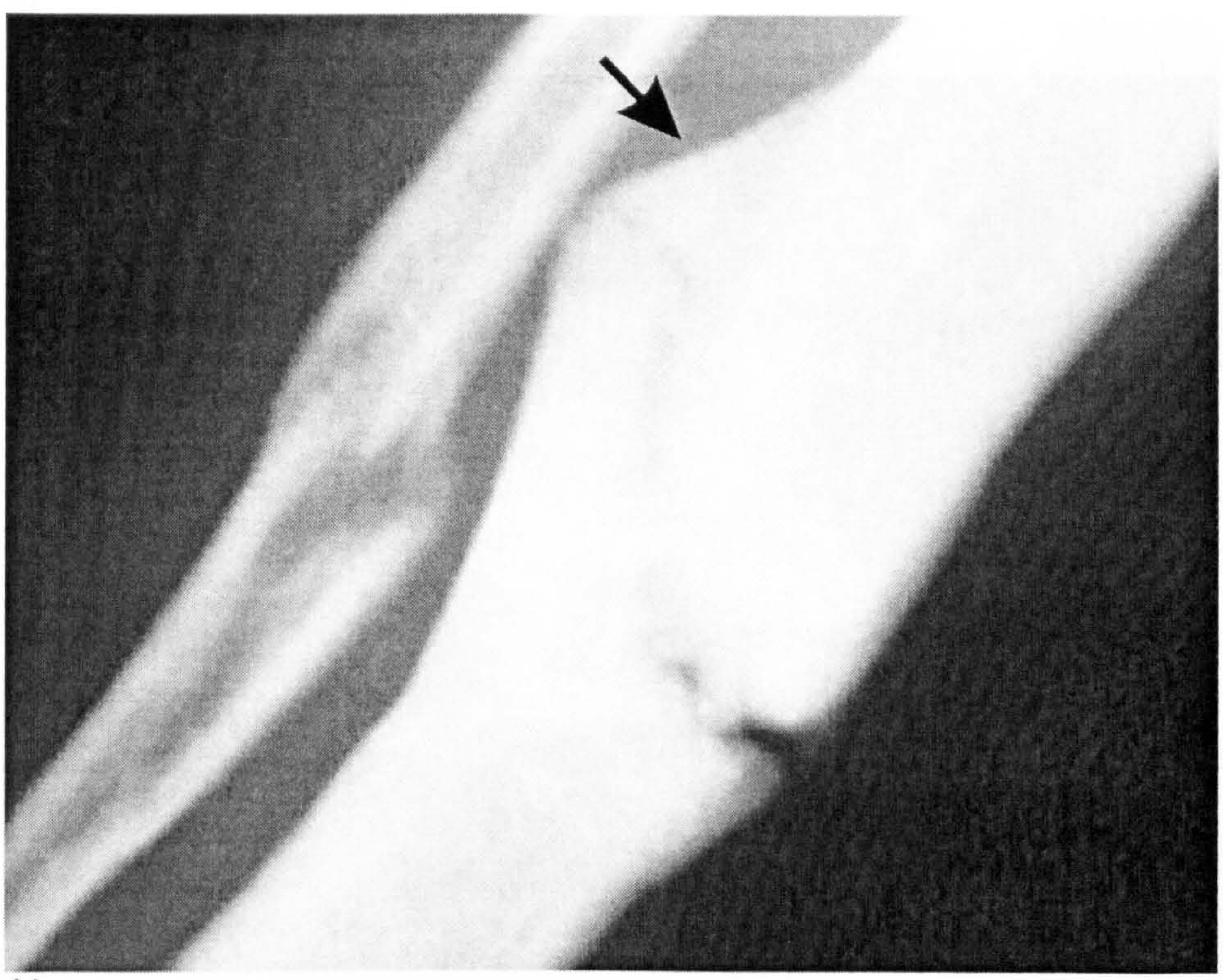


Figure 8 Radiograph of patient T6 showing that frame components can obscure areas of interest on the radiographs.

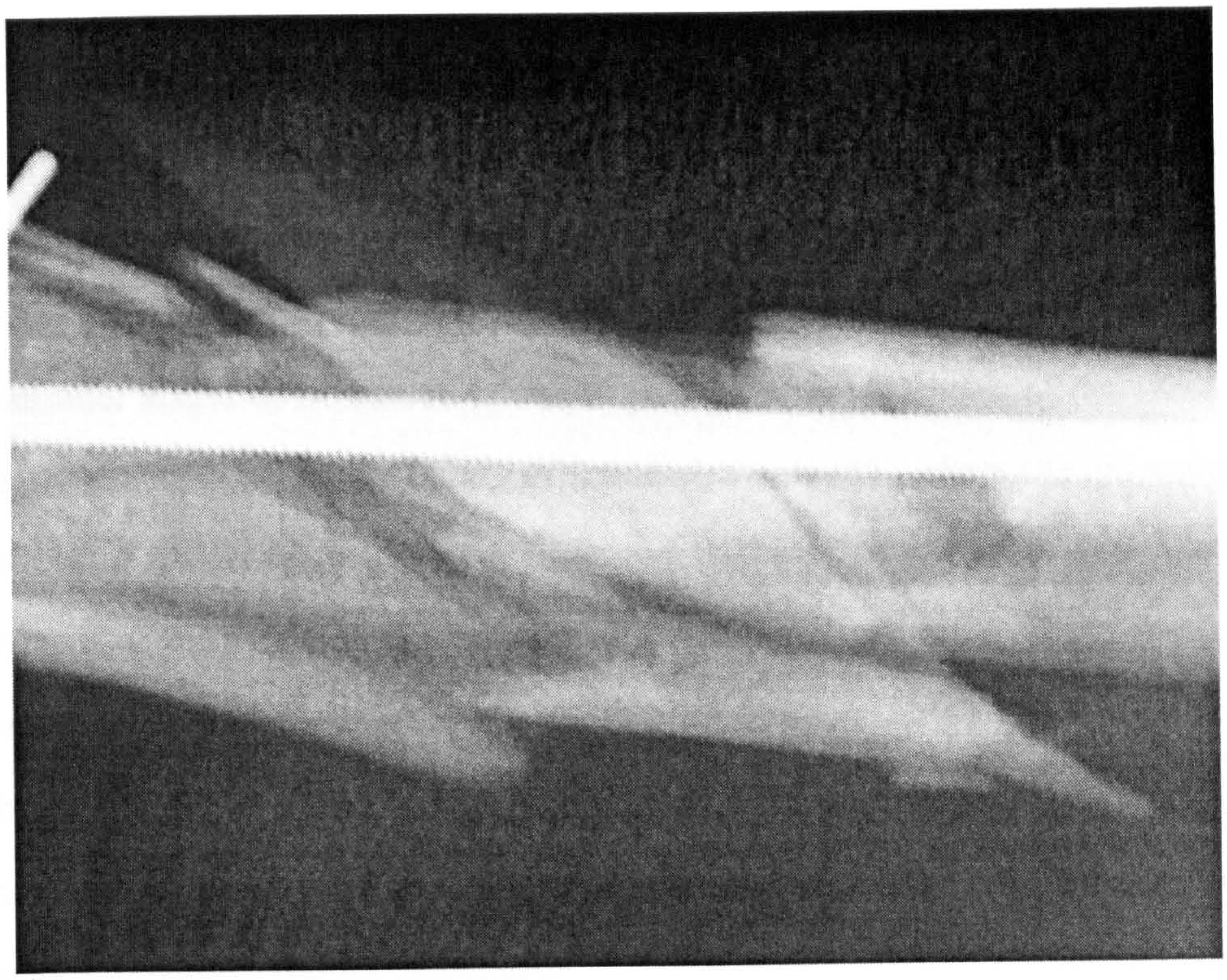
Therefore, in the absence of an adequate technique for assessing fracture healing surgeons adopt a conservative approach. To avoid the possibly drastic consequences of premature frame removal, the duration of fixation may be much longer than is necessary in many cases. This results in increased patient morbidity and the possibility of secondary complications, such as pin tract infections, arising (**55**). The prolonged duration of fixation also has significant implications on the cost of treatment.

a)

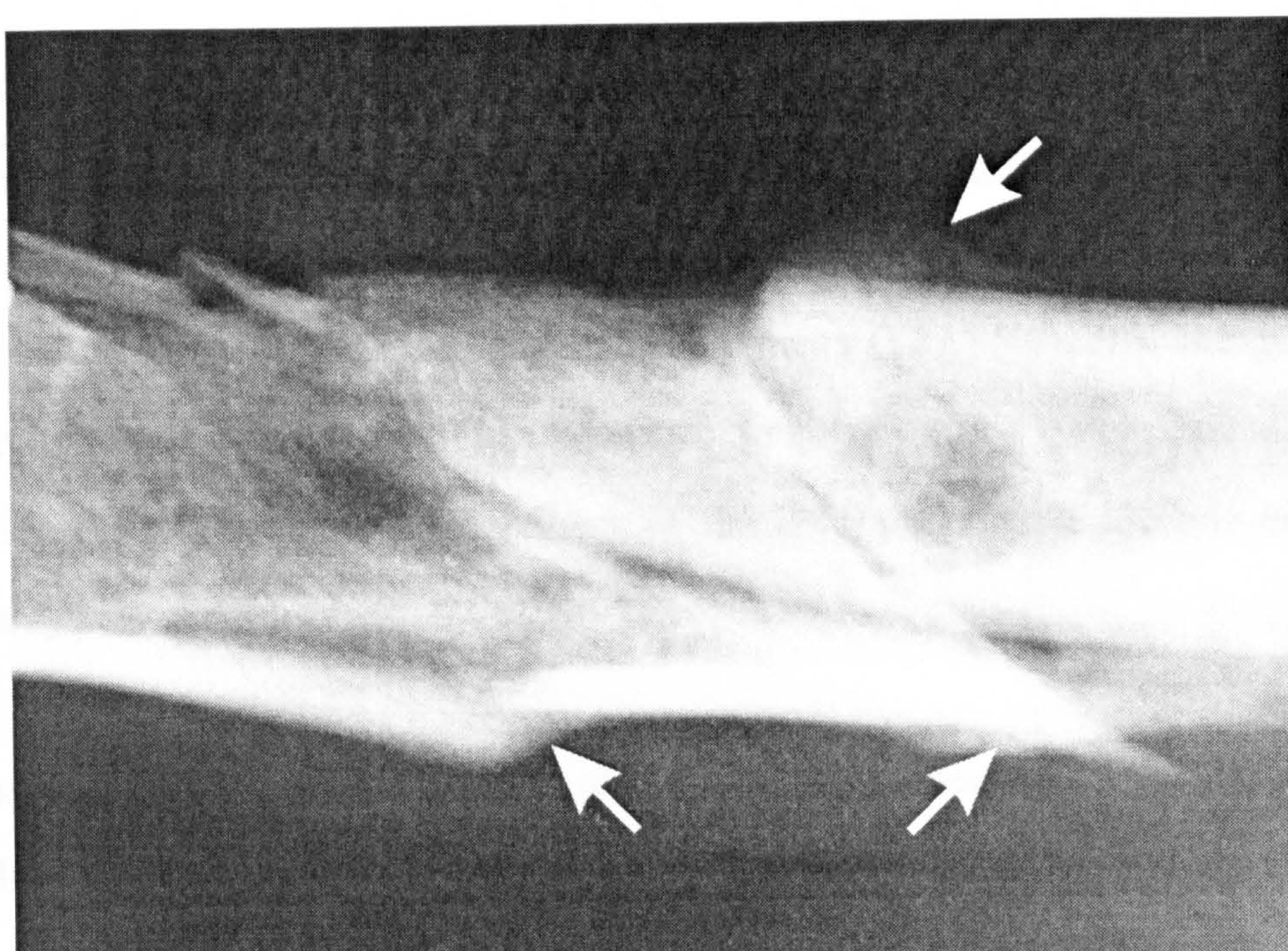


b)

Figure 9 Radiographs of patient T2; a) the day after frame application and, b) the day after frame removal 52 weeks later. Abundant callus material can be seen on the latter radiograph; particularly noticeable is the buttress indicated by the arrow.



a)



b)

Figure 10 Radiographs of patient F1; a) 2 weeks after frame application and, b) the day after frame removal, 18 weeks later. The fracture has united with the formation of little callus material; the small areas of callus material present are indicated by the arrows.

The development of a technique for the routine non-invasive evaluation of fracture healing has been the topic of orthopaedic research for more than 50 years (56). In addition to indicating when frame removal might safely proceed (57-61) the existence of a method of routinely monitoring fracture healing could prove useful in several other stages of treatment. It would give an early indication of disturbed bone healing processes (57) or the failure of frame elements (61), allow the assessment of the effect of differing treatment regimes on fracture healing (62), and allow the assessment of the effect of the severity of the initial injury on healing time (63). It has been shown that alteration of the stability of fixation during the healing process can have beneficial effects on both the quality and rate of healing (11, 12, 20); another possible use of routine monitoring of fracture healing would be to indicate when such alteration should take place.

Several techniques which could potentially be used for the routine monitoring of fracture healing have been developed over recent years. These include: ultrasound imaging (64), quantitative computed tomography (QCT) (65), radiographic photodensitometry (66), single-photon absorptiometry (SPA) (67), dual energy x-ray absorpiometry (DEXA) (68, 69), resonance frequency (70-72), ultrasound wave velocity (73,74), and the measurement of the deformation of a fracture-external frame system under load (52, 57-61, 75-78).

Ultrasound imaging is a useful additional tool in the assessment of fracture healing but does not allow quantitative evaluation of the mechanical integrity of the fracture site. The ratio of the speed of sound through fractured bone and a contralateral unfractured bone has been used as an index of healing but for a number of reasons suffers from poor reproducibility. Radiographic photodensitometry can be used to indirectly measure the bone mineral content (BMC) but there are many sources of error with this technique. QCT can be used to measure bone mineral density (BMD), and SPA and DEXA the BMC; the bone's modulus of elasticity can then be derived from empirical relations. Reasonable correlation can be obtained with QCT (65) though marrow fat content has a significant effect on accuracy (79). However, the technique has little usefulness for monitoring because of the high radiation dose per BMD determination; exposures with SPA and DEXA are lower but so are the correlations. In addition, all three techniques are relatively expensive. Resonance frequency would poorly evaluate fractures stabilised with external fixation because of the difficulty of assessing the contribution of the frame.

By contrast to the techniques described above, measuring deformation of the fracture-external frame system under load provides the most direct method of monitoring the increase in fracture stiffness as healing occurs. The fracture is considered as a structural member of variable stiffness in parallel with the external fixator. Initially, the fracture is incapable of carrying all, if any, of the load. A portion of the load is transmitted through the frame inducing strain in the connecting rods and deflecting the pins. As the fracture heals the proportion of the load it is able to carry increases and the strain in the rods and deflection of the pins reduce. By taking initial measurements of the strain and/or deflection and relating these to subsequent measurements taken under the same loading conditions, the degree of healing can be monitored. The technique has the potential advantages of being extremely cheap and simple, and does not involve subjecting the patient to radiation exposure.

The objective of the study described in sections 4 and 5 was to investigate methodologies for a) determining the absolute axial stiffness of a healing fracture at any point in time with an external circular frame *in-situ* and, b), routinely monitoring the increase in axial stiffness of a healing fracture relative to the axial stiffness of the external circular frame.

CHAPTER 3. Biomechanics of the Ilizarov Frame

As a result of the spectacular results reported of the Ilizarov method and frame, a considerable number of studies of the biomechanics of the original device, *i.e.* that in which bone fragments are held by tensioned fine wires, have been published. In the main these studies have concentrated on the mechanical characteristics of the frame in its pristine condition, *i.e.* immediately after application. A few have commented on the changes that may occur to the mechanical characteristics of the frame with fatigue and yielding of the components as treatment progresses, but none have adequately quantified such changes. Section 3.1 describes a study, undertaken by the present author, in which finite element analysis was used to investigate the effects of yielding of the fine wires following functional weight bearing.

To date very few studies have been published specifically dealing with the biomechanics of the modified Ilizarov frame, *i.e.* that in which bone fragments are supported by half pins. The assumption appears to be that such frames behave in similar ways to other half pin frames such as the unilateral frame. Given the greater geometric complexity of the modified Ilizarov frame over unilateral frames, and its ability to provide multiple planes of fixation with a single unit, this seems unlikely. Section 3.2 describes a study, undertaken by the present author, in which finite element analysis was used to investigate the contribution of individual components to the axial compression stiffness of the modified frame.

3.1 The Original Ilizarov Frame

The mechanical environment imposed on a fracture by an external fixator is generally accepted to be the most significant factor in determining both the rate of fracture healing and the mode by which union occurs (**9,10**). The exact nature of the optimal mechanical environment for fracture healing is unknown but it is possible to infer certain aspects from the numerous studies of interfragmentary motion characteristics which have been conducted. These studies have shown that low levels of cyclical axial strain in the fracture gap promote fracture healing (**20-25**), whereas higher levels inhibit union because bone is resorbed at the segment ends to reduce the level of strain (**26**). Cyclic bending micromotion appears to have little effect on fracture healing and bone remodelling (**80-81**); shear strain in the fracture gap promotes the formation of fibrocartilage and is therefore deleterious to the healing outcome (**17**).

Therefore, the ideal fixator would be one with a non-linear axial stiffness and a high shear stiffness, *i.e.* one which allows low amplitude cyclical axial motion, but inhibits high amplitude axial motion and shear motion of the bone fragments. Many previous studies have suggested that the Ilizarov frame fulfilled these criteria because the crossed tensioned fine wires which support the bone fragments give the device a high shear stiffness and an axial stiffness which is markedly non-linear. Additionally, the wires allow purely axial motion in response to an axial load whereas fragment motion in response to an axial load in fixators using half pins will usually have a small shear component because the pins act as cantilevers. However, these studies have either ignored the fact that plastic deformation will occur in the tensioned fine wires (**18, 48, 82-86**), merely noted that it will occur (**87, 88**) or have only quantified it for the most simple case (**89, 90**). The objective of the study described in this section was to determine the significance of such deformation to the long term performance of frames used for treating lower limb fractures by the use of finite element analysis. The effect of parameters such as wire diameter, pre-tension and ring diameter on the magnitude of the deformation were also investigated. In a preliminary stage, mechanical tests were conducted on Ilizarov wires to obtain data on the material properties of the wires for the finite element models.

3.1.1 Mechanical Testing of Fine Wires

12 wires of 1.8 mm diameter were chosen at random from stock supplied by Smith and Nephew Richards Inc. (Memphis, TN, USA). The wires are manufactured to American Society for Testing and Standards (ASTM) F138 grade 2 stainless steel standards; the permissible chemical composition ranges are given in table 1. The wires were subjected to destructive tensile tests using a Zwick Universal Testing Machine 1478 (Zwick Testing Machines Ltd., Leominster, U.K.) in accordance with BS (EN) 10218. The wires were inserted through two riders, one of which carried an linear variable-differential transformer (l.v.d.t.), the other provided surface for the plunger of the l.v.d.t. to abut to; a gauge length of 100 mm was used, figure 11. Displacement was measured with the l.v.d.t. and load read from the Zwick machine. From the results of these tests average values of Young's modulus, yield stress and the parameters defining the material's post yield behaviour were obtained for use in the finite element analysis. These are summarised in table 2, and a stress/ strain curve for one of the wires is shown in figure 12.

Table 1 Chemical composition of ASTM F138 grade 2 stainless steel wire for surgical implants (**91**).

Element	Composition (%)
Carbon	0.030 max.
Manganese	2.000 max.
Phosphorus	0.025 max.
Sulphur	0.010 max.
Silicon	0.750 max.
Chromium	17.00 to 19.00
Nickel	13.00 to 15.50
Molybdenum	2.00 to 3.00
Nitrogen	0.100 max.
Copper	0.500 max.
Iron	balance

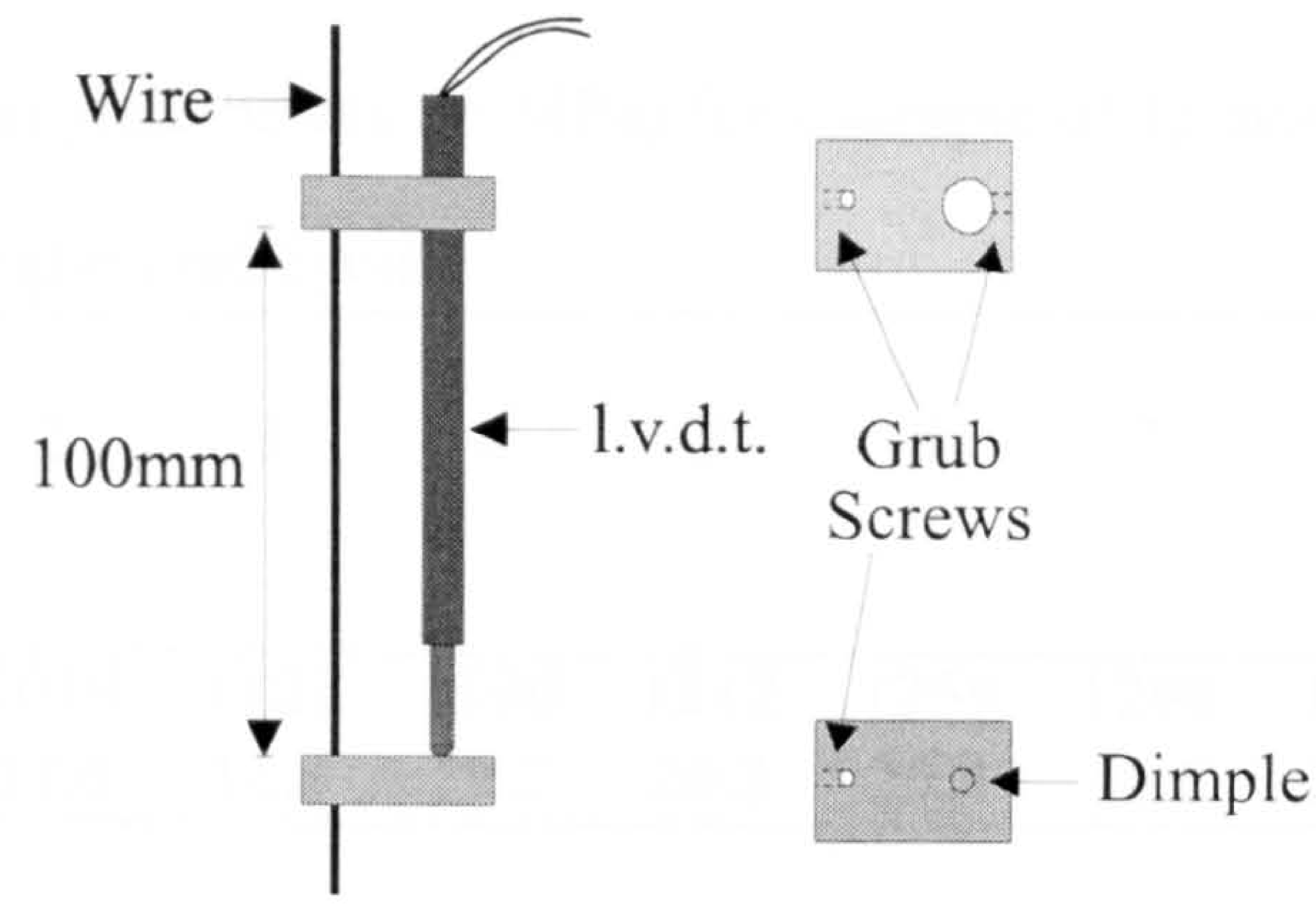


Figure 11 Rig for mechanical testing of wires.

Table 2 Results of tensile tests on a sample of 12 steel wires.

	Young's Modulus / GPa	Yield Point / MPa	Peak Stress / MPa	Stress at Failure / MPa
Mean	151	685	1337	1287
S.D.	6.6	9.2	60.7	66.5

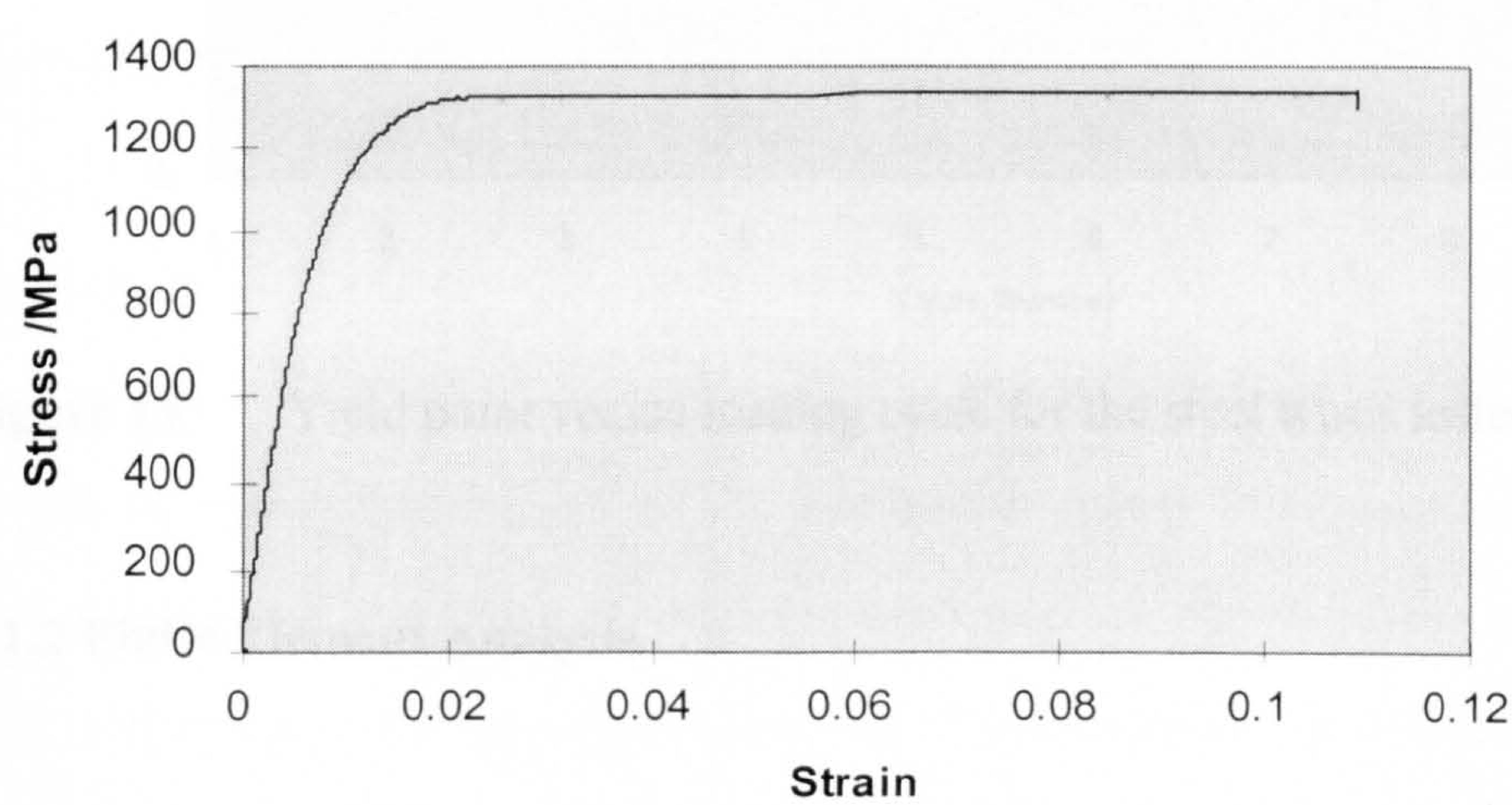


Figure 12 Complete stress/ strain curve for one of the steel wires tested.

A further 12 wires were then tested to assess the degree of work hardening which would occur to the wire material. Each wire was subjected to 10 cycles of loading in which it was stressed until it began to yield; the yield point for each cycle was recorded. The results are summarised in Table 3 and figure 13.

Table 3 Mean yield points (in MPa) for a sample of 12 steel wires subjected to multiple load cycles.

Cycle Number	1	2	3	4	5	6	7	8	9	10
Mean	685	1019	1122	1190	1212	1259	1296	1311	1312	1315
S.D.	9.4	17.6	18.4	19.2	20.3	25.4	26.6	28.1	28.3	30.1

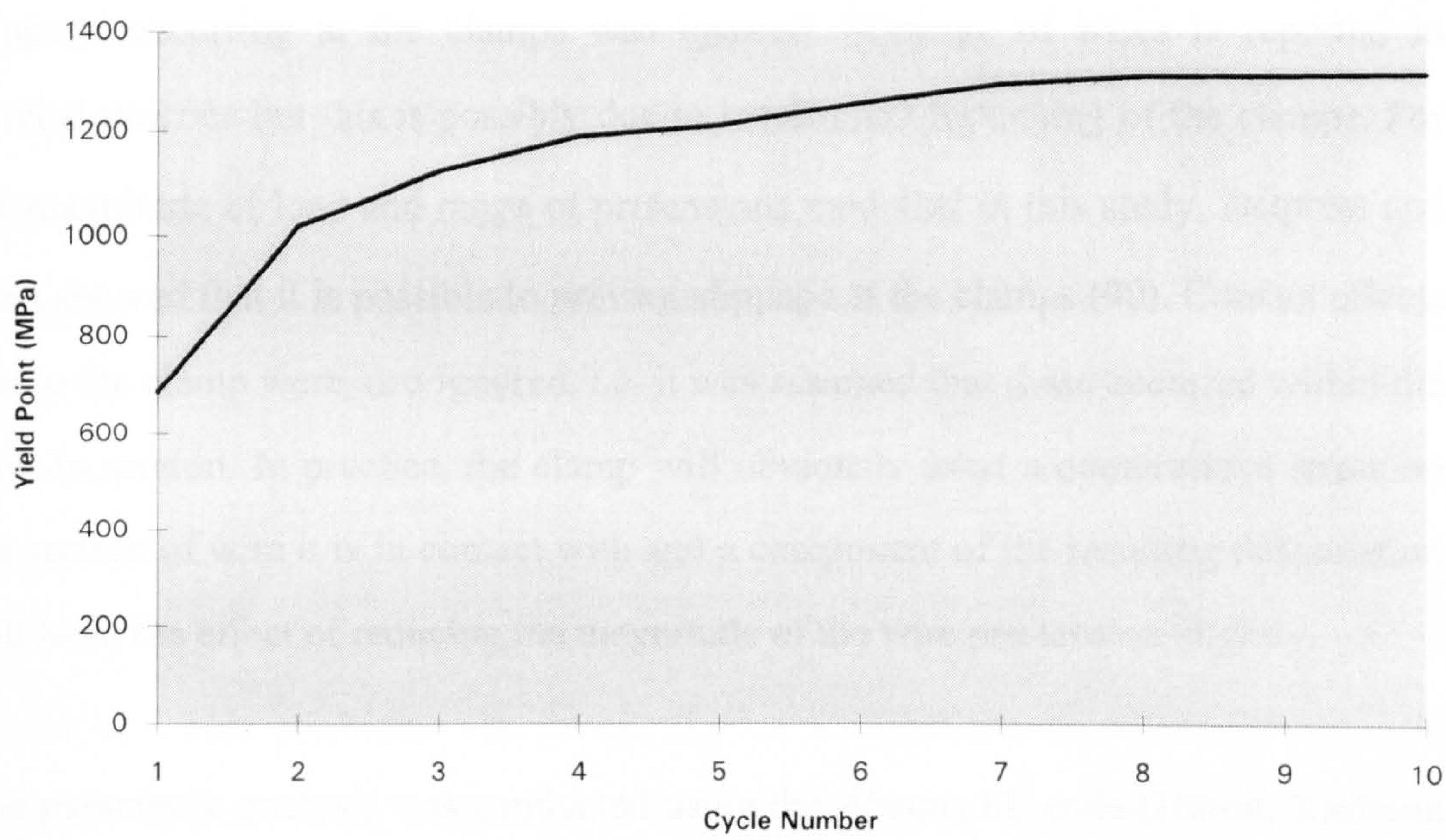


Figure 13 Yield point versus loading cycle for the steel wires tested.

3.1.2 Finite Element Analysis

Under weight bearing loads, the wires, rings and other frame elements deflect; the majority of the deflection takes place in the wires. In order to simplify the analysis it was assumed that all deflection resulting from an applied load would occur in the wire. This assumption can be justified for two reasons. Firstly, the wires are the least stiff of the frame elements. Secondly, to minimise slippage of the bone fragments, the wires are generally attached to the rings, and hence the other frame elements, in pairs which are as mutually perpendicular as other factors will allow. Hence, any effect on the ring caused by one wire deflecting in response to an applied load will be opposed by the effect of the other wire. Additionally, as the wires are symmetrical about a plane perpendicular to their midpoint, as can be seen from figures 5 and 7, and it was only necessary to model half the span of the wire. Reducing the size of the model in this way increases computational efficiency.

The wires were modelled as built in at the clamped ends, *i.e.* the possibility of slippage occurring at the clamps was ignored. Slippage of wires is reported in clinical practice but this is possibly due to insufficient tightening of the clamps. For the magnitude of load and range of pretensions modelled in this study, Delprete and Gola showed that it is possible to prevent slippage at the clamps (90). Contact effects due to the clamp were also ignored, *i.e.* it was assumed that these occurred within the built-in section. In practice, the clamp will obviously exert a compressive stress on the section of wire it is in contact with and a component of the resulting deformation will have the effect of reducing the magnitude of the wire pre-tension slightly.

The parametric analysis was conducted using the Abaqus FE code (Hibbit, Karlsson & Sorensen (UK) Ltd., Warrington, U.K.) and involved the use of seven models (Table 4) whose dimensions reflected commonly used frame configurations. Each model consisted of 4012, 8 noded brick elements. An elastic-plastic material model was used in which the post-yield behaviour of the material was defined by a series of 30 straight lines approximating to the stress-strain curve obtained from the mechanical tests. It was assumed that the material would unload along a line parallel to the elastic portion of this stress-strain curve.

Table 4 Frame configurations modelled.

Model No.	Wire Diameter /mm	Ring Diameter /mm	Wire Pretension /N
1	1.8	180	981
2	1.5	180	981
3	2.0	180	981
4	1.8	140	981
5	1.8	220	981
6	1.8	180	589
7	1.8	180	1472

For each of the models a section of wire was modelled of length $L/2 - \delta_x$, where L is the length of the whole wire span, *i.e.* the internal ring diameter, and δ_x is the displacement required to produce the appropriate level of pre-tension. One end of the section of wire was then restrained, i.e. the nodes on one of the circular faces were assigned zero degrees of freedom, (Figure 14a). A displacement of δ_x was then applied to the other end of the wire model in the direction of the major dimension of the wire (Figure 14b). A second displacement, δ_y, equivalent to that which would be caused by a load of 200 N, was then applied to the unrestrained end of the wire in a direction perpendicular to the first displacement, in ten equal increments (Figure 14c).

A load of 200 N approximates to the loading to which each wire would be subjected in a frame having six wires per bone segment in an 80 kg patient during walking, assuming perfect load sharing between the wires. The model was interrogated to determine the magnitude of the equivalent load and the tension in the wire after each increment. The second displacement was then removed and the model allowed to reach equilibrium, again in ten increments.

A further two models were used to investigate the effect of multiple cycles of loading on the tension in the wires. These models had the same configuration as model 1 (see

Table 4) but were subjected to ten cycles of loading. In one of the models the yield point was set to 685 MPa and to 1315 MPa in the other. These values correspond to those determined for the first and tenth load cycles by non-destructive tensile testing (see Table 3). The model was interrogated after each cycle of loading to determine the magnitude of the residual displacement and the tension in the wire.

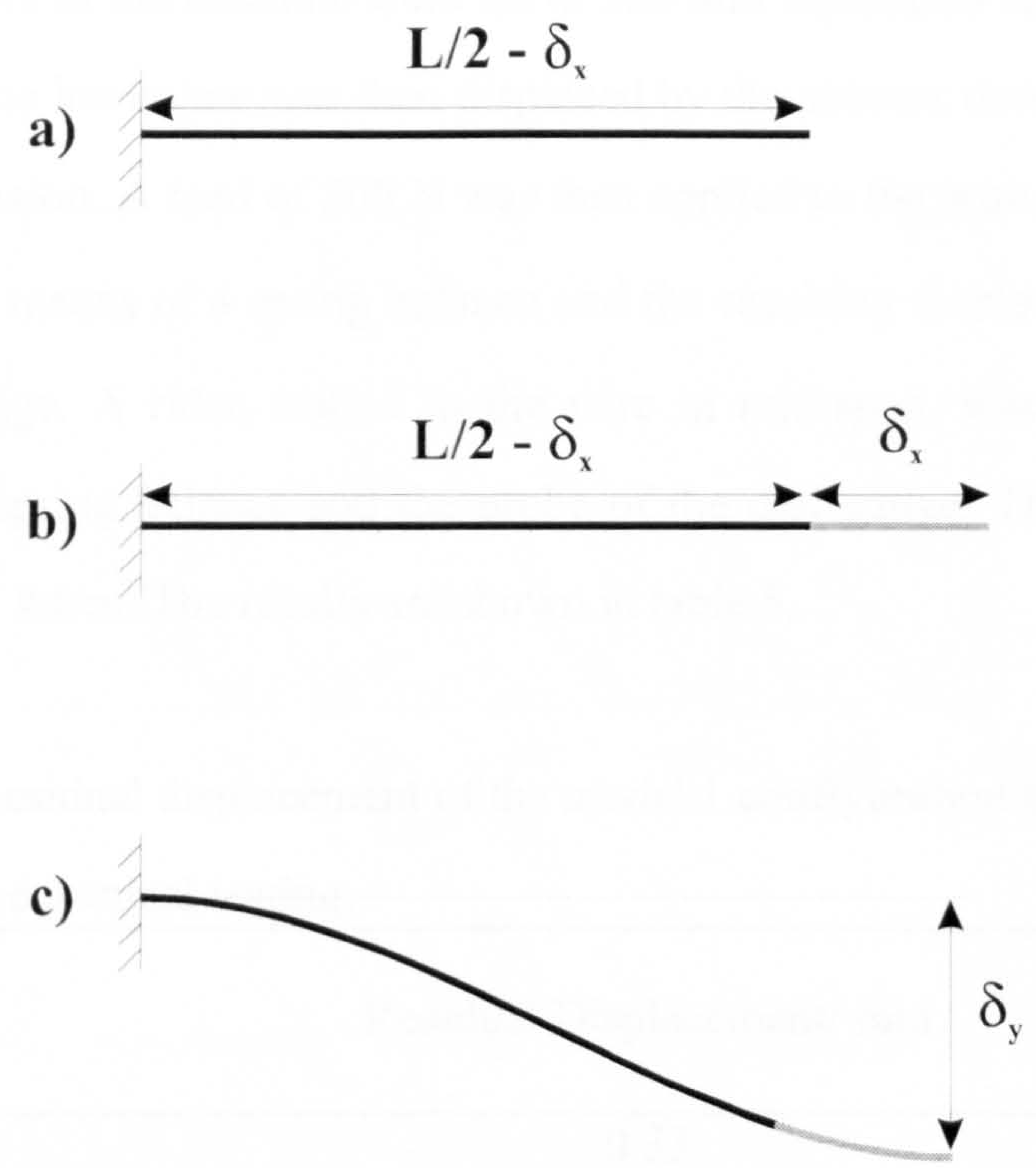


Figure 14 Schematic showing the three principle stages in the execution of the models: a) section of wire, of length $L/2$ - δ_x, was modelled with one end restrained, b) a displacement of δ_x was applied to the free end to produce the required level of pre-tension, and c) a displacement of δ_y, equivalent to that which would be caused by a load of 200 N was applied.

3.1.3 Mechanical Testing

In order to validate the finite element analysis one of the configurations was mechanically tested, using the Zwick Universal Testing Machine, to provide comparative values of residual displacement. The configuration of model 1 was chosen because it had the median values of the parameters varied in the parametric analysis. The jaws of the machine were set to 180 mm separation and a wire inserted between them; the lower jaw was then displaced by the amount necessary to produce the 981 N pretension. A load of 200 N was then applied to the wire, perpendicular to its long axis, by means of a spring balance and the resulting displacement measured using a dial gauge. A rider, bolted to the wire in mid-span, was used to prevent slippage of the spring balance and the probe of the dial gauge. The procedure was performed on 12 wires. The results are shown in table 5.

Table 5 Residual displacement of the model 1 configuration determined by mechanical testing.

	Residual Displacement/ mm
Mean	0.33
S.D.	0.03

3.1.4 Results

Figure 15 shows the non-linear relationship between the stiffness of a wire and the magnitude of the applied load. It also clearly shows the inadvisability of reporting that a particular frame configuration has a particular stiffness without stating the range for which this is valid **(85)**. The values of the residual displacement and tension for the seven models after a single load cycle are shown in table 6 together with the reduction in tension expressed as a percentage of the pre-tension. The results for model 1, *i.e.* a 1.8 mm diameter wire, 180 mm long, pre-tensioned to 981 N, can be compared with the results obtained from the direct mechanical testing of this configuration, see table 5. The figure predicted for the residual displacement by the finite element model, 0.31 mm, is approximately 6 % lower than the 0.33 mm determined by the direct mechanical tests. Given the simplifications which are inherent to the finite element model, see section 3.1.2, the figures show a reasonably close correlation.

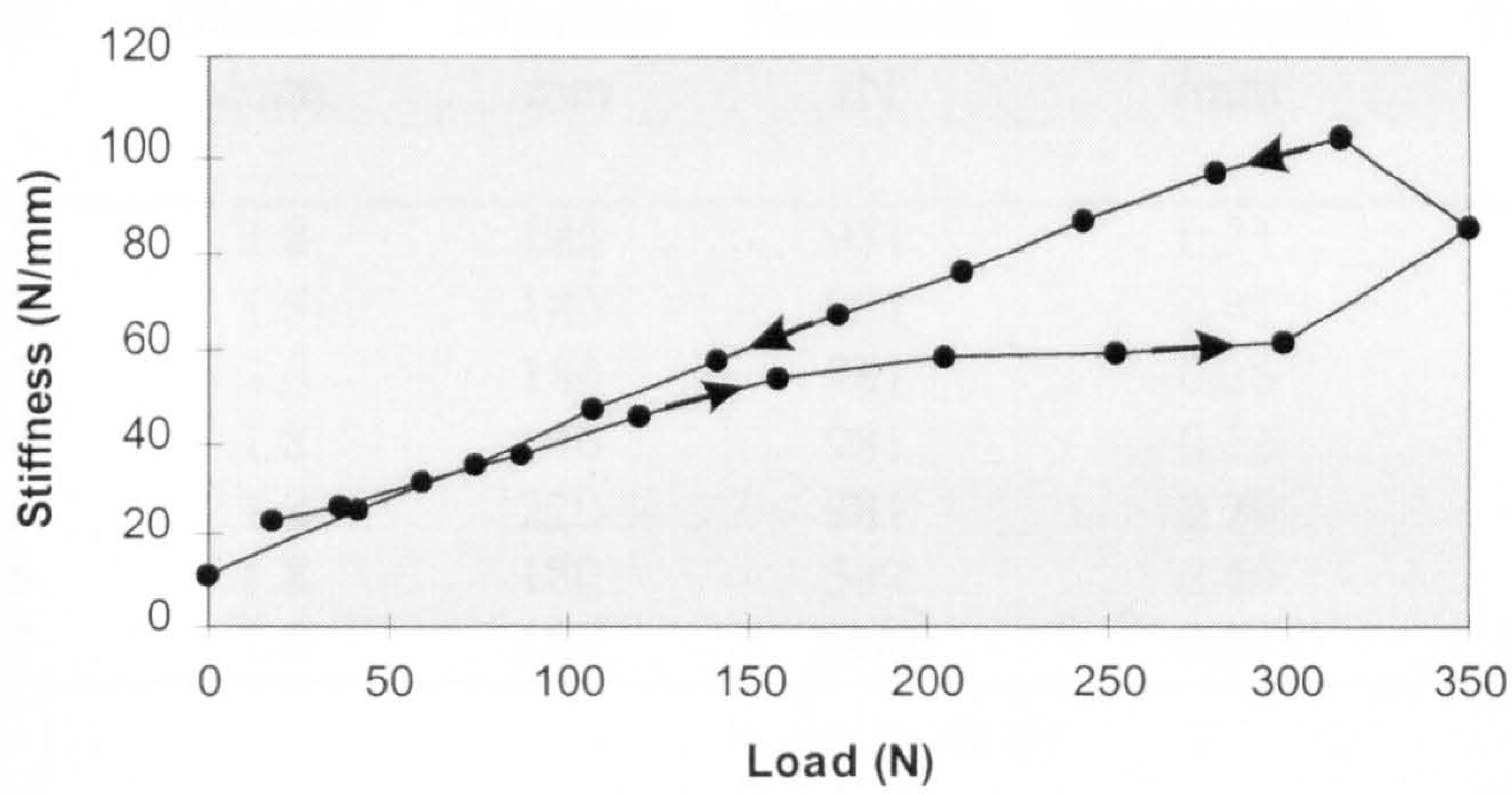


Figure 15 The relationship between the magnitude of a load applied perpendicular to the midpoint of a tensioned wire and the stiffness displayed by the wire over a single load cycle. Wire diameter, ring diameter and pre-tension were 1.8 mm, 180 mm and 981 N respectively.

The model 1 results can also be compared with those published by Delprete and Gola (**89, 90**). They applied an axial load of 200 N per wire to 1.8 mm wires pre-tensioned to 1000 N and held in clamping bolts tightened to various torques. At values of clamping torque high enough to prohibit slippage of the wires they obtained residual lateral displacements of approximately 0.3 mm. Unfortunately the ring diameter, *i.e.* wire length, is not stated and so a direct comparison between their experimental results and the FE models of this study is not possible. However, the value of wire length has a relatively minor effect on the value of residual displacement, as can be seen by comparing the results of models 1, 4 and 5, and the results are in general agreement.

Table 6 Residual displacement and tension for the seven models after a single loading cycle of 200 N.

Model No.	Wire Diameter /mm	Ring Diameter /mm	Wire Pretension /N	Residual Displacement /mm	Residual Tension /N	Reduction in Tension /%
1	1.8	180	981	0.31	900	8.3
2	1.5	180	981	0.42	659	32.8
3	2.0	180	981	0.26	920	6.2
4	1.8	140	981	0.33	873	11.0
5	1.8	220	981	0.29	919	6.3
6	1.8	180	589	0.40	522	11.4
7	1.8	180	1472	0.27	1244	15.5

Load-displacement curves are shown for the seven models in figures 16, 17 and 18. From these it can be seen that ring diameter (*i.e.* wire length) has the most pronounced effect on the stiffness of the wires followed by wire diameter and pre-tension in that order. Hence, to maximise stiffness wire diameter and pre-tension should be maximised and ring diameter minimised. Tension-displacement curves are shown for the seven models in figures 19, 20 and 21. From these it can be seen that ring diameter (*i.e.* wire length) has a fairly minor effect on the magnitude of the residual displacement (and hence, the degree of de-tensioning) but wire diameter and pretension have a marked effect. To minimise the degree of de-tensioning which occurs upon loading, the diameter of the wires should be maximised and the pre-tension minimised, i.e. stiff pins such as those used in the Hoffman device should be adopted.

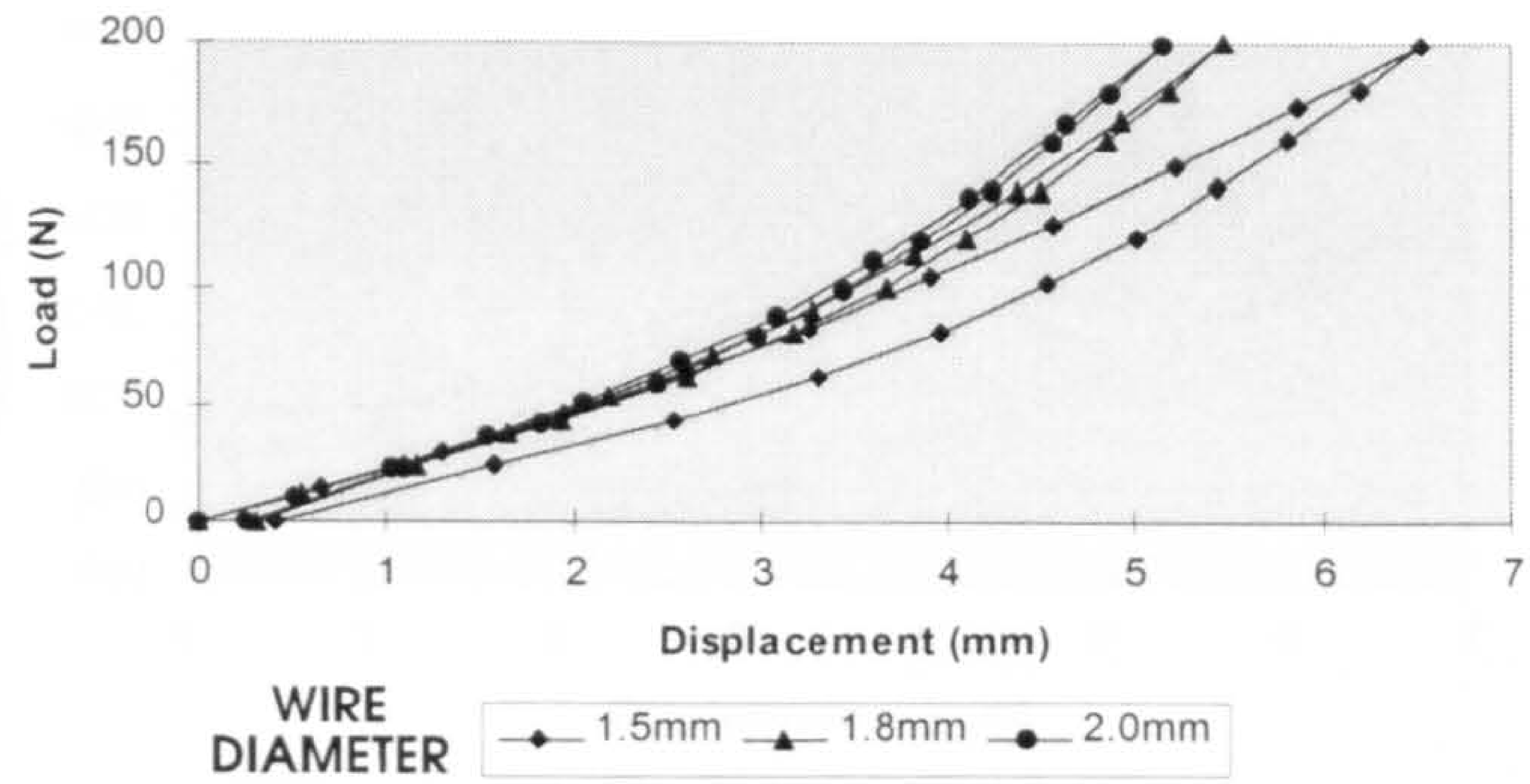


Figure 16 The effect of wire diameter on the relationship between load and displacement over a single load cycle; ring diameter and pre-tension are 180 mm and 981 N respectively for all three wires.

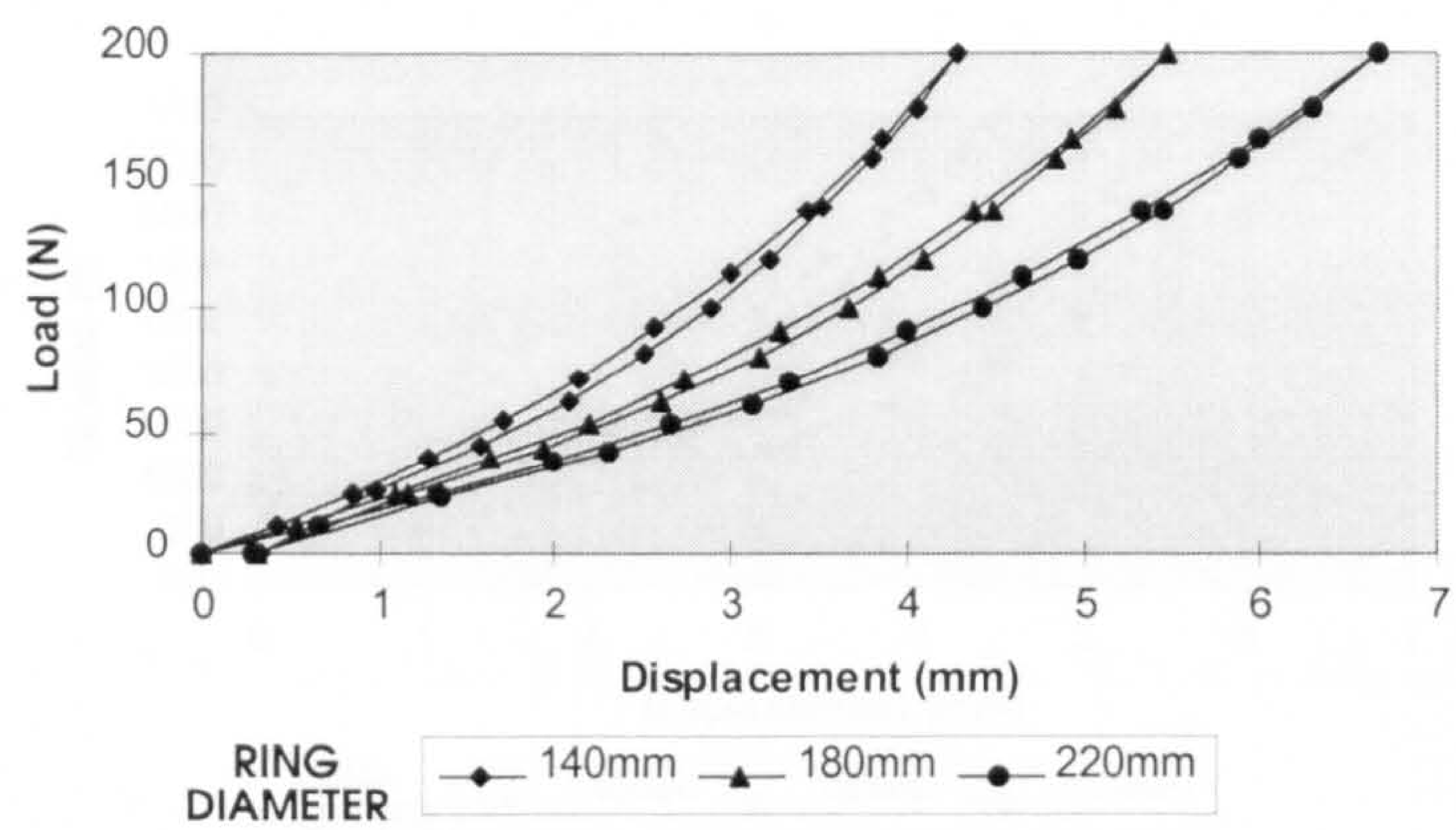


Figure 17 The effect of wire length (ring diameter) on the relationship between load and displacement over a single load cycle; wire diameter and pre-tension are 1.8 mm and 981 N respectively for all three wires.

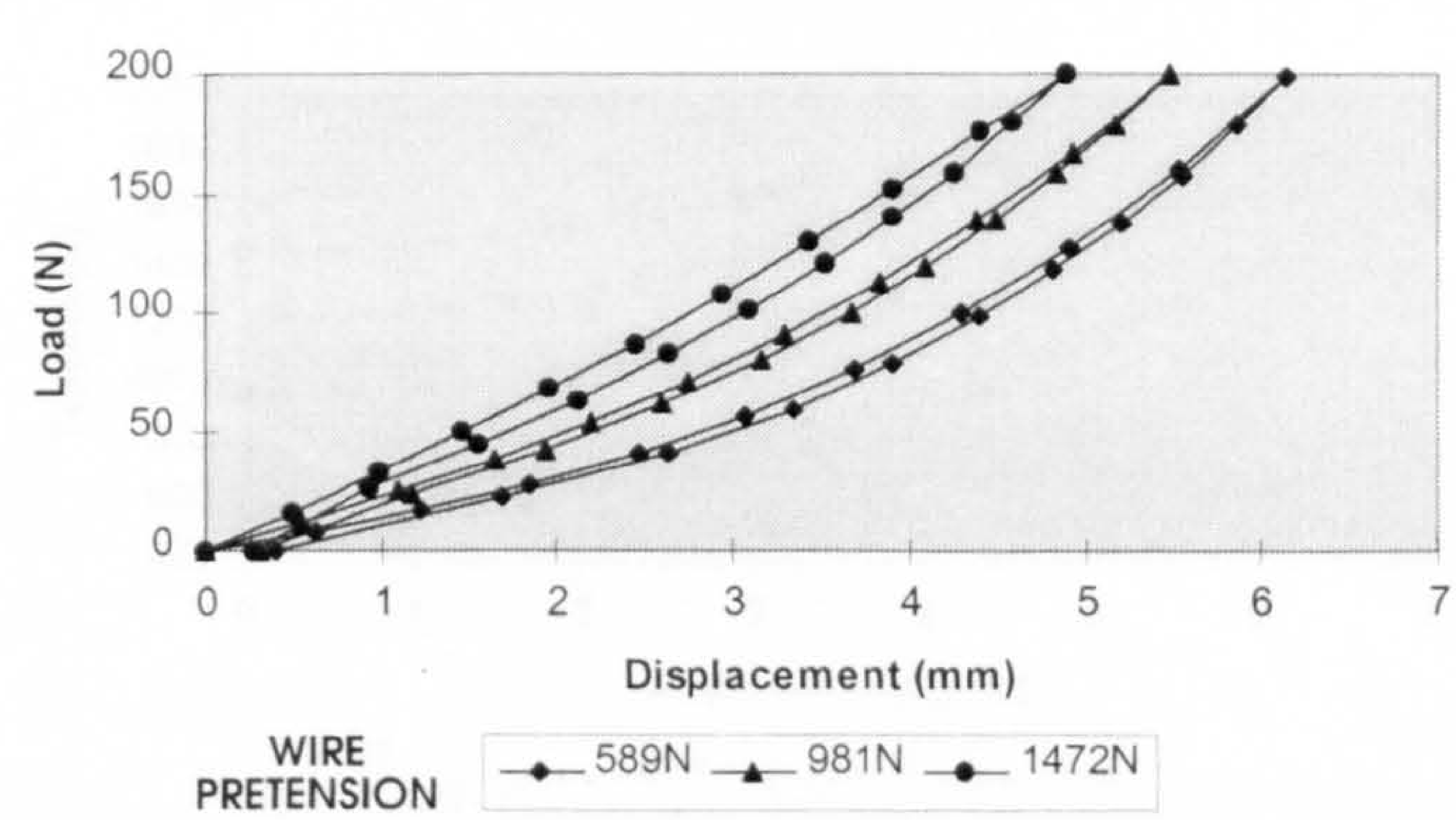


Figure 18 The effect of wire pre-tension on the relationship between load and displacement over a single load cycle; wire and ring diameter are 1.8 mm and 180 mm respectively for all three wires.

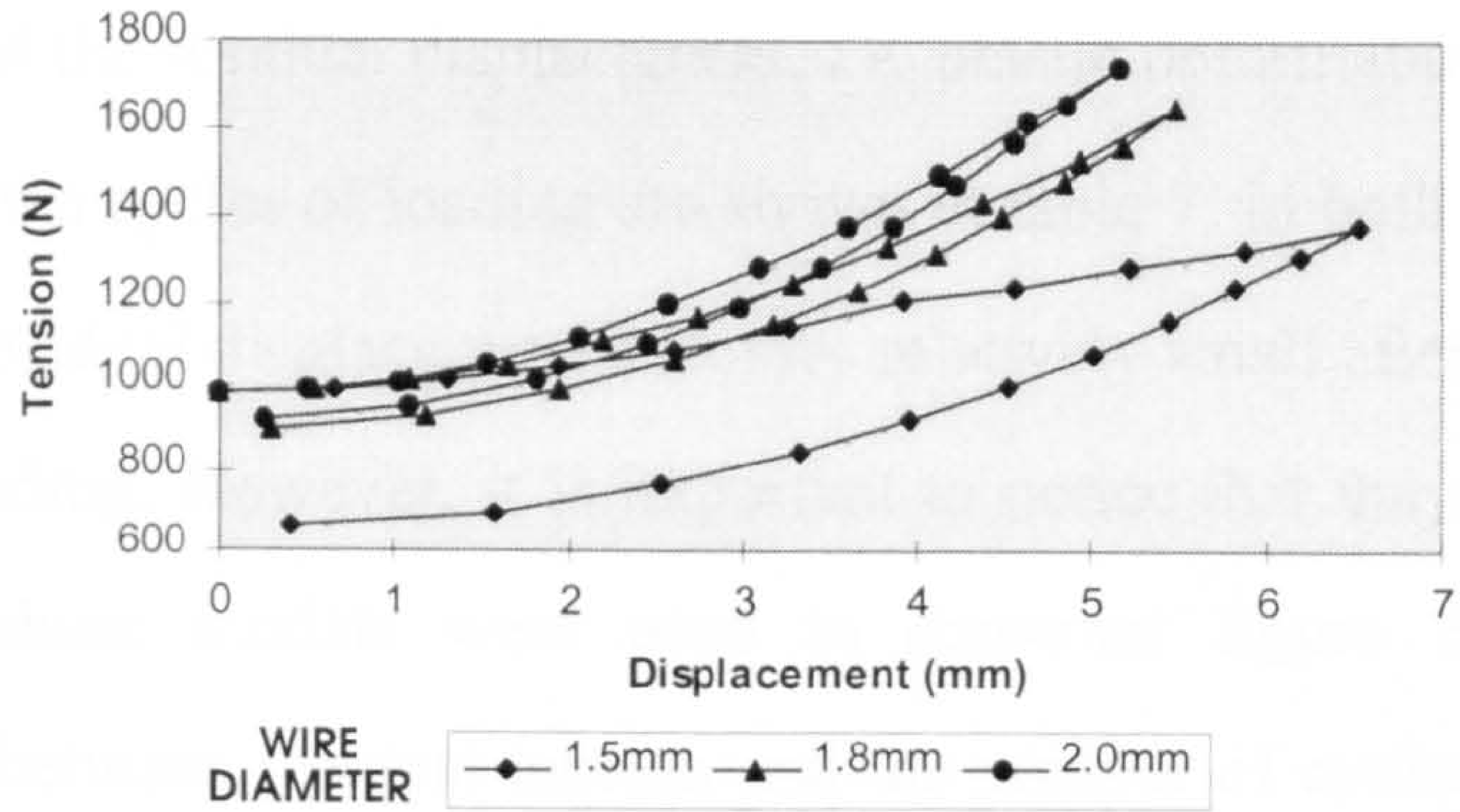


Figure 19 The effect of wire diameter on the relationship between tension and displacement over a single load cycle; ring diameter and pre-tension are 180 mm and 981 N respectively for all three wires.

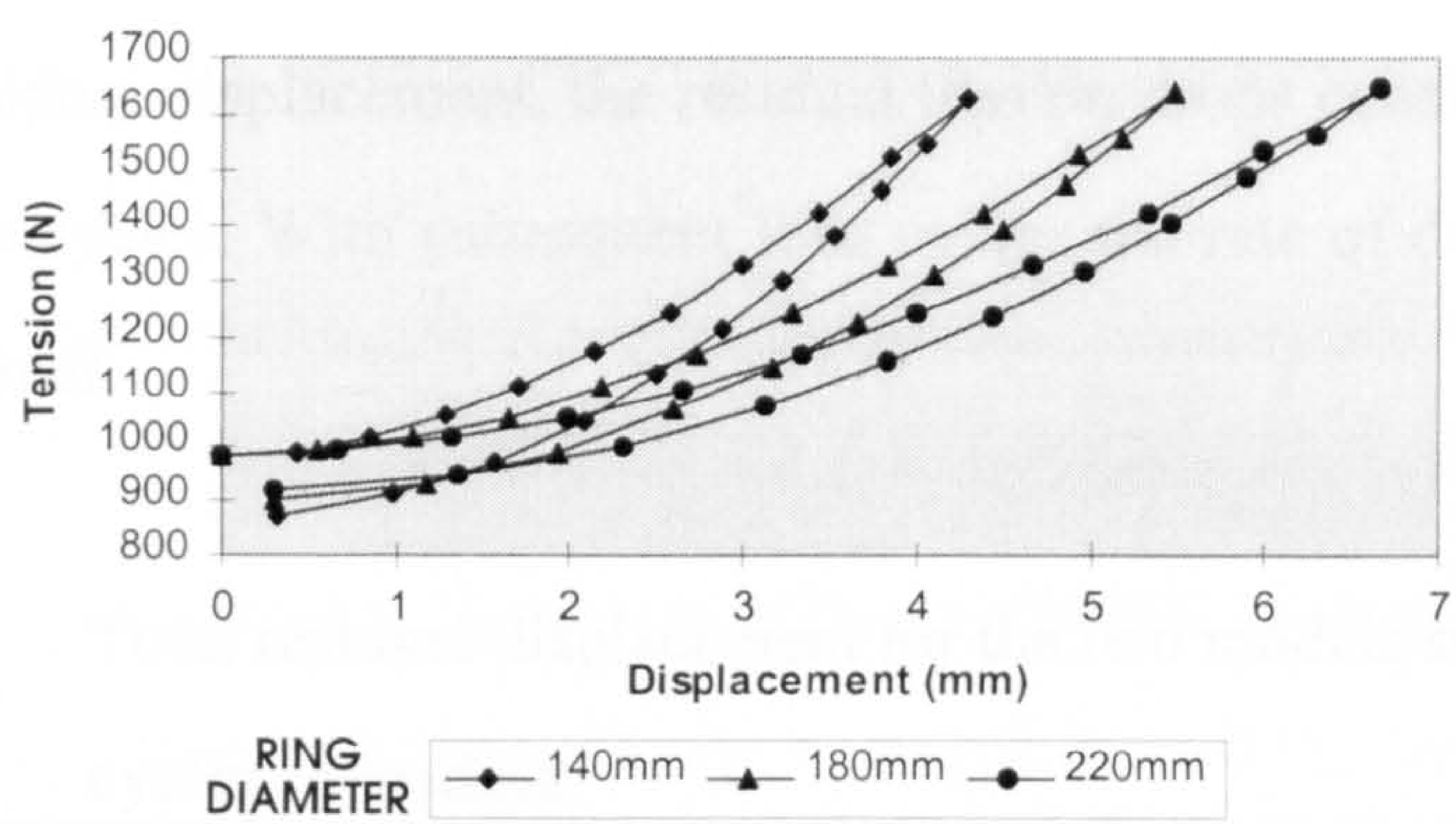


Figure 20 The effect of wire length (ring diameter) on the relationship between tension and displacement over a single load cycle; wire diameter and pre-tension are 1.8 mm and 981 N respectively for all three wires.

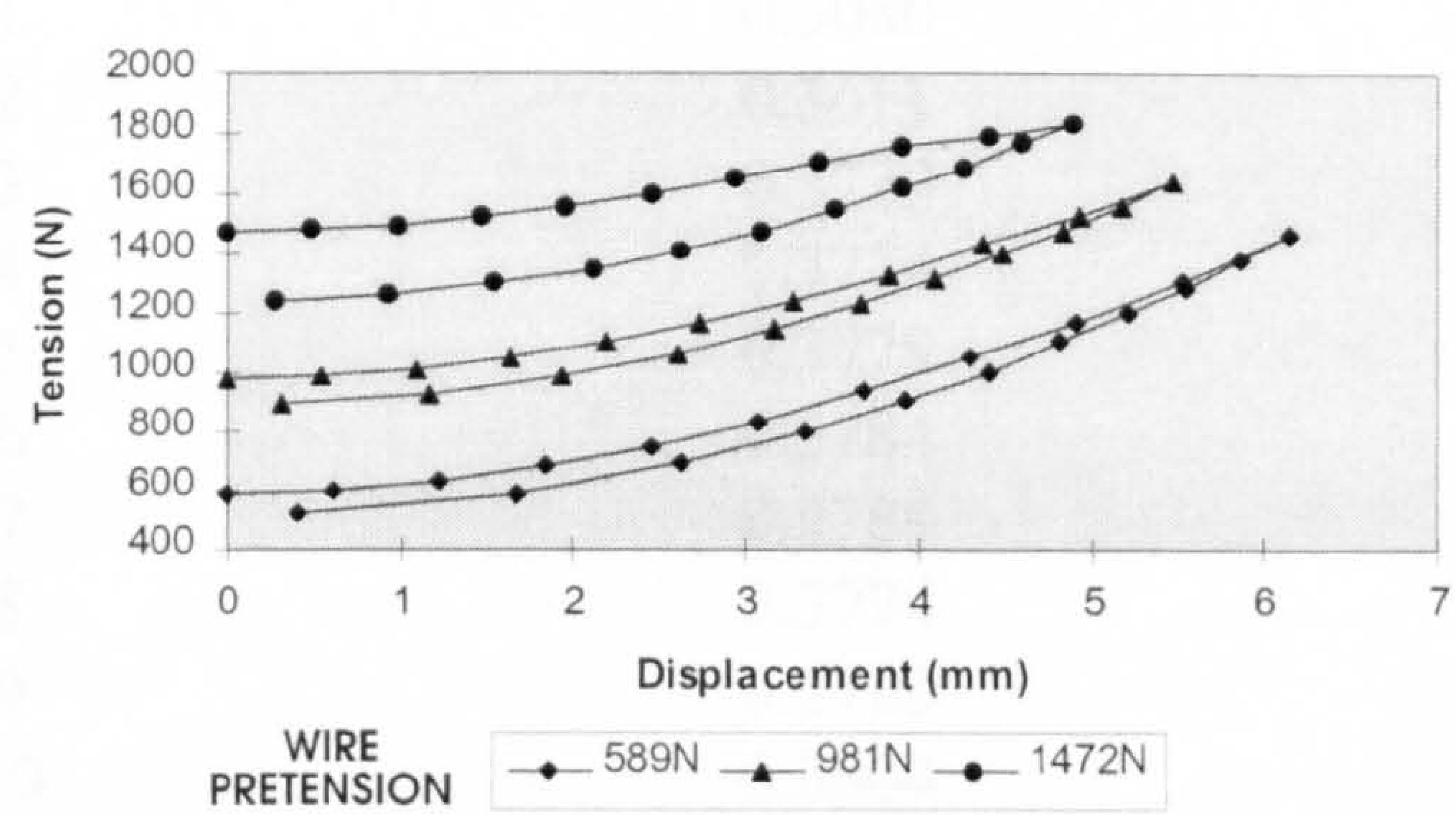


Figure 21 The effect of wire pre-tension on the relationship between tension and displacement over a single load cycle; wire and ring diameter are 1.8 mm and 180 mm respectively for all three wires.

The values of the residual displacement, *i.e.* plastic deformation, for the two models subjected to ten cycles of loading are shown in table 7. In both cases the incremental increase in residual displacement becomes relatively small after the first two or three cycles of loading. However, it is important to notice that they do not become zero. Data from these models were used to construct figure 22 which shows the relationship between residual tension and the number of cycles of loading to which the wire has been subjected. The solid line represents a wire which exhibits no work hardening and the dotted line one in which the yield point increases to its maximum value after a single cycle of loading. The actual value of the residual tension after a particular load cycle will be contained in the envelope formed by these curves. As with the residual displacement, the residual tension drops considerably after the first two or three cycles. With subsequent load cycles the rate of de-tensioning becomes relatively small.

Table 7 Total residual displacement for the two models subjected to multiple cycles of loading.

	Total Residual Displacement /mm	
Cycle Number	Yield Point = 685 MPa	Yield Point =1315 MPa
1	0.3080	0.0638
2	0.3611	0.0710
3	0.3729	0.0723
4	0.3774	0.0726
5	0.3779	0.0730
6	0.3784	0.0733
7	0.3789	0.0737
8	0.3794	0.0740
9	0.3799	0.0744
10	0.3804	0.0747

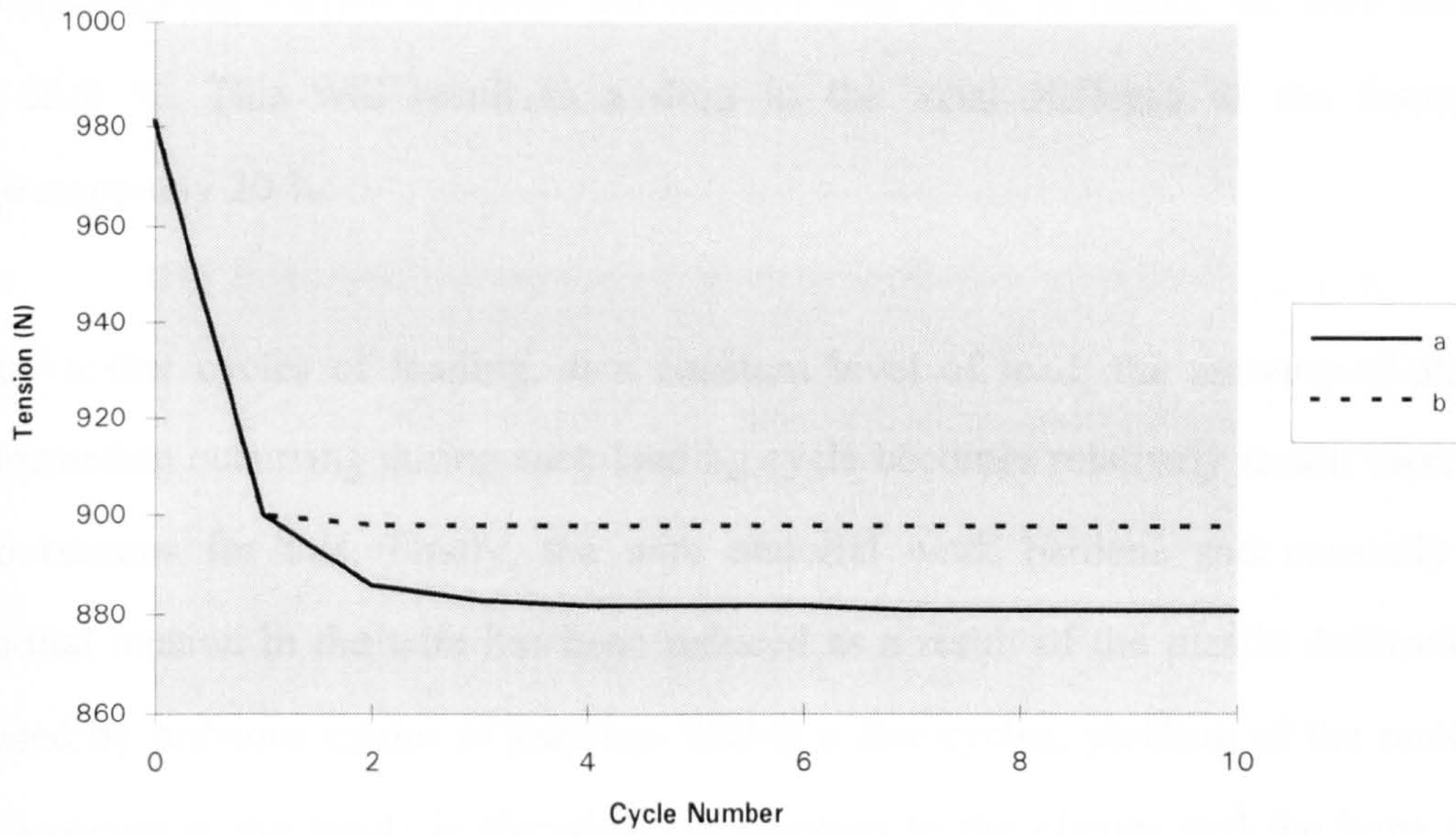


Figure 22 Residual tension versus cycle of loading: a) for the hypothetical case where no work hardening occurs, and b) for the hypothetical case where the yield point assumes its maximum value after a single cycle of loading. The actual value of residual tension after a particular load cycle is contained in the envelope formed by these curves.

3.1.5 Discussion

The tensioned fine wires used in the Ilizarov frame on lower limbs undergo significant plastic deformation when first exposed to moderate loads, such as those imposed by slow walking. The plastic deformation causes a reduction in wire tension, resulting in a reduction in overall frame stiffness and, hence, compromises the frame's ability to resist shear motion and high amplitude axial motion.

For a specific example, consider a frame having six wires per bone segment in which rings of 180 mm diameter, wires of 1.5 mm diameter, and wire pretensions of 981 N are used. When the frame is subjected to a single load cycle with a magnitude of 200 N per wire, *i.e.* that to which it would be subjected by a patient weighing 80 kg during walking, sufficient plastic deformation will occur to reduce the wire tension by 32.8 %. This will result in a drop in the axial stiffness of the frame of approximately 20 %.

After a few cycles of loading, at a constant level of load, the amount of plastic deformation occurring during each loading cycle becomes relatively small; there are two reasons for this. Firstly, the wire material work hardens and secondly the residual tension in the wire has been reduced as a result of the plastic deformation caused by previous cycles of loading. Within a few cycles, yielding of the material only occurs at the bends in the wire, *i.e.* adjacent to the clamps and the bone. The magnitude of the stress in these regions is a function of the stress induced in the wire by the residual tension and the stress induced in the wire upon deflection. Eventually the residual tension in the wire is reduced to a level where the maximum stress reached in these areas during loading no longer exceeds the yield point of the work hardened material. In the case of a 180 mm long wire with a diameter of 1.8 mm and an initial pretension of 981 N, yielding will cease when the residual tension has fallen to about 785 N, or about 80 % of the pretension.

However, it is possible that before such a point is reached, painful stimuli in response to shear and high amplitude axial motions would result in the patient reducing the amount of weight borne by the limb and hence the load borne by individual wires. This is an important consideration because one of the main advantages of the Ilizarov frame is that it supposedly allows a high degree of patient mobility at an early stage of treatment. Ilizarov stated that one of the most significant factors required for optimal bone regeneration was functional activity of the muscles and the joints of the limb (**39**). Such activity stimulates the supply of blood to the limb as a whole and, hence, to the fracture site. Additionally, functional weight-bearing will give rise to cyclical axial strain in the fracture gap. If this strain is of relatively low magnitude, *i.e.* the axial stiffness of the frame is sufficiently high for the loads imposed, it will also stimulate osteogenic processes.

It is, of course, possible to re-tension the wires once they have plastically deformed, *i.e.* to restore the tension in them to the level of the initial pretension. When subjected to loading, the re-tensioned wires will not display the high levels of plastic deformation, per load cycle, that they did on initial loading because the wire material will be thoroughly work hardened. They will however, plastically deform where they are bent, *i.e.* adjacent to the clamps and the bone. Plastic deformation in these regions will continue to occur until the residual tension in the wire is again reduced to a level where the maximum stress reached in these areas during loading no longer exceeds the yield point of the work hardened material. As the material in these regions yields there will be a corresponding gradual reduction in overall frame stiffness.

A possible solution to this problem would be to regularly re-tension the wires. However, for this solution to be effective it is necessary to establish how gradually the reduction in frame stiffness occurs. Therefore, there is a requirement for further study to establish the magnitude and frequency of loads applied to the frame by patients. The frequency of loading has been studied in dynamised Orthofix unilateral frames **(92)**, but to the author's knowledge this has never been attempted with the Ilizarov frame. Another area which should be considered is the effect of loads induced on the frame by distraction osteogenesis; a couple of studies have shown that these can be as high as 1000N **(93, 94)**.

The Ilizarov frame was developed at the Kurgan All-Union Centre for Restorative Traumatology and Orthopaedics, in the former USSR. Patients at the centre came from all parts of the former USSR and remained as in-patients throughout the course of their treatment. In such an environment it is presumably relatively easy for the surgeon to make regular, responsive, minor adjustments to the frame, such as re-tensioning of the wires. In the West, patients treated with the Ilizarov technique tend to be treated as out-patients and may only receive clinical supervision once a month. It is beneficial, therefore, to adopt systems which require the minimum of maintenance. Hence, the use of half pins of 5-8 mm in diameter, instead of wires, to support bone fragments may provide a better solution and have the additional advantage of reducing painful soft tissue transfixion.

3.1.6 Titanium Wires

Following the presentation of the above material at the Circular Frame Users Group annual meeting in April, 1996, the author was asked by Smith and Nephew Richards Incorporated (Memphis, Tennesee, United States of America) to evaluate some titanium wires for use with the Ilizarov frame. The procedure was exactly as outlined in section 3.1.1 above; a summary of the results is given in table 8, and a stress/ strain curve for one of the wires is shown in figure 23.

Table 8 Results of tensile tests on a sample of 12 titanium wires.

	Young's Modulus / GPa	Yield Point / MPa	Peak Stress / MPa	Stress at Failure / MPa
Mean	95	672	968	952
S.D.	1.5	31.5	25.4	20.5

From these figures it can be seen that the Young's modulus of the titanium wire material is rather low at c. 95 GPa; a value of 120 GPa would be expected for pure titanium. This may be due to the manufacture process, or alternatively, the material may be an alloy. The yield point of the titanium wires is very similar to that of the steel wires though the values of peak and failure stress are much lower. The problem identified with the steel wires above was that, due to the geometry of the Ilizarov device, high stresses were induced in the regions of the wires adjacent to the clamps in response to even relatively low applied loads. This resulted in yielding and, therefore, de-tensioning of the wires which, in turn, lead to a loss of frame stability. Given the similar yield point and lower peak stress this problem is likely to be even more significant with titanium wires.

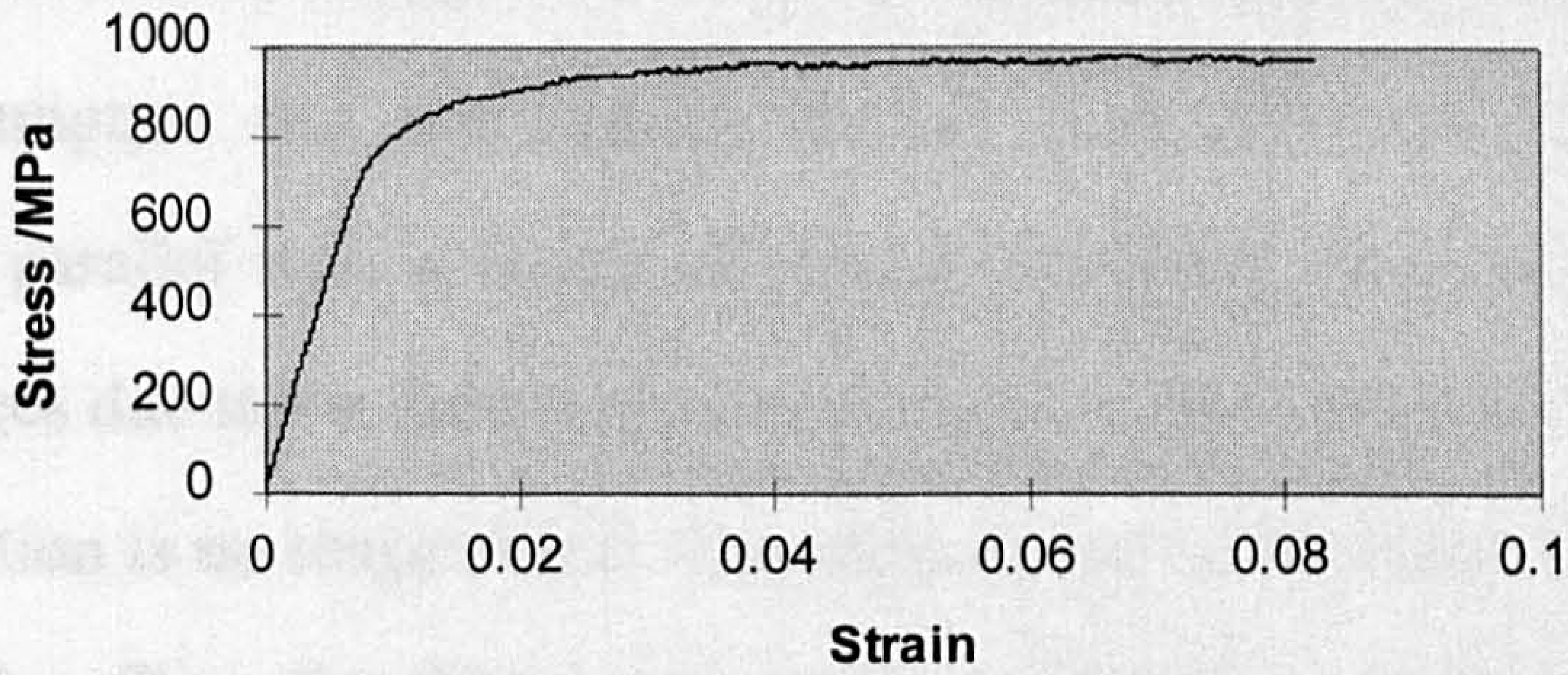


Figure 23 Complete stress/ strain curve for one of the titanium wires.

3.2 The Modified Ilizarov Frame

Only a few studies have been published specifically dealing with the biomechanics of the modified Ilizarov frame, *i.e.* that in which bone fragments are supported by half pins. Most of these studies have been comparisons of the mechanical characteristics of the modified frame with those of the original frame (**95, 96**). One interesting study attempted to develop a method for estimating the axial stiffness of modified frames by inspection (**97**). Unfortunately, the only parameters considered were the number of half pins and the length of the bone to ring offset, *i.e.* the distance from the pin/bone interface to the pin/clamp interface. The objective of the study described in this section was to investigate the contributions made to the axial compression stiffness of the modified frame by all the main structural components, *i.e.* rings, connecting rods, and pins. The study was conducted using finite element analysis.

There were two main motivations for the study. Firstly, it would be useful to be able to estimate the stiffness characteristics of a particular frame merely by inspection and to understand how alterations to the frame's configuration will affect them. As mentioned above, the optimal biomechanical environment for the promotion of rapid healing changes as the process proceeds. If the surgeon is to be able to maintain an optimal mechanical environment he needs to know how to achieve it. Secondly, relative stiffness monitoring, which was investigated as part of this project, is based on the assumption that the healing fracture is a structural member of variable stiffness in parallel with a frame of constant stiffness. If the configuration of the frame changes due to the failure of components, or their removal for clinical reasons, this assumption is no longer valid. Therefore, it would be useful to have a method of estimating the effect of such changes on the axial stiffness of the frame.

3.2.1 Finite Element Models

The objective of the study was to investigate the contribution of individual frame components to the overall axial stiffness of the frame. A range of 15 frame configurations, composed of steel rings and rods, and titanium half pins, was modelled. The configurations of the models are shown in table 9; mesh plots of model 4 are shown in figure 24. To reduce the study to manageable proportions, some of the dimensions of the components were fixed in all models. In clinical practice the most commonly used rings are those with a diameter of 180 mm; the most common diameter for pins and rods is 6 mm. Therefore, components of these dimensions were used in all the models.

A 20 mm osteotomy in a cylindrical bone of 35 mm diameter, with a cortical thickness of 5 mm, was used as a fracture model. In configurations where there were more pins than rings, the extra pin, or pins, were attached to the ring, or rings, nearest to the fracture gap; no ring had more than two pins attached. Where two pins were attached to a ring, they were modelled subtending an angle of 34° between them. Rods were modelled equidistantly spaced around the ring, except in the case of the 4 and 5 rod configurations where the spacing was only approximately equidistant (an 180 mm diameter Ilizarov ring has 42 holes arranged around its median circumference).

Table 9 Modified frame configurations modelled.

Model No.	No. of Rings	Vertical Ring Spacing (mm above, and below, the centre of the fracture gap)	No. of Pins	No. of Rods
1	6	30, 100, 140	12	6
2	6	30, 100, 140	12	5
3	6	30, 100, 140	12	4
4	6	30, 100, 140	12	3
5	6	30, 100, 140	12	2
6	6	30, 100, 140	12	1
7	6	30, 100, 140	10	3
8	6	30, 100, 140	8	3
9	6	30, 100, 140	6	3
10	4	30, 100	8	3
11	4	30, 140	8	3
12	4	100, 140	8	3
13	2	30	4	3
14	2	100	4	3
15	2	140	4	3

To simplify the analysis a number of assumptions were made. It was assumed that no slippage could occur at either the pin/bone interface or at the pin/clamp interface. In practice, this was achieved by meshing the models so that the nodes on the pin meshes would be coincident with the nodes of the bone and ring at the interfaces; the coincident nodes were then tied. The rods were similarly assumed to be built in where they passed through the rings. It was therefore, not necessary to model pin clamps or rod locking nuts. Another simplification involved the geometry of the rings. Preliminary models showed that a 4 mm thick solid ring was approximately structurally equivalent to the 6 mm thick perforated Ilizarov ring in diametrical compression, tension and torsional loading. As a solid ring can be modelled with considerably fewer elements than a perforated one, the rings were modelled with only as many holes as was required for the connecting rods. Finally, as the frame configurations were symmetrical about a plane through the centre of the fracture gap, parallel to the rings, it was only necessary to model half the frame.

The finite element analysis was conducted using the Abaqus FE code (Hibbit, Karlsson & Sorensen (UK) Ltd., Warrington, U.K.). The largest model, model 1, consisted of 7904, 8-noded brick elements and 2160, 6-noded wedge elements. The smallest model, model 15, consisted of 1280, 8-noded brick elements and 546, 6-noded wedge elements. A perfect elastic-plastic material model was used, *i.e.* one in which the stress/strain curve runs parallel to the abscissa after yield. Values for the Young's modulus and the yield stress of the frame components were taken from the manufacturer's literature (Smith and Nephew Richards Inc., Memphis, TN, USA). For the cortical bone, 20 GPa and 150 MPa were used for the Young's modulus and yield point respectively (**98, 99**); these values were reduced by two orders of magnitude for the cancellous bone (**100**). As mentioned above, for reasons of symmetry it was only necessary to model half of the frame. Therefore, the connecting rods were truncated at their midpoints, which coincided with the centre of the fracture gap, and restrained. A displacement of 10 mm was applied in ten equal increments to the top surface of a disk of steel, 1 element thick, which was modelled on the top surface of the bone, *i.e.* that farthest from the fracture gap. The disk of steel was necessary to prevent local distortion of the mesh in the region of the cancellous bone. The model was interrogated after each increment to determine the magnitude of the equivalent load, and the displacement the central node in the lower surface of the bone, *i.e.* that adjacent to the fracture gap. From these values the average value of the axial stiffness over each increment was calculated.

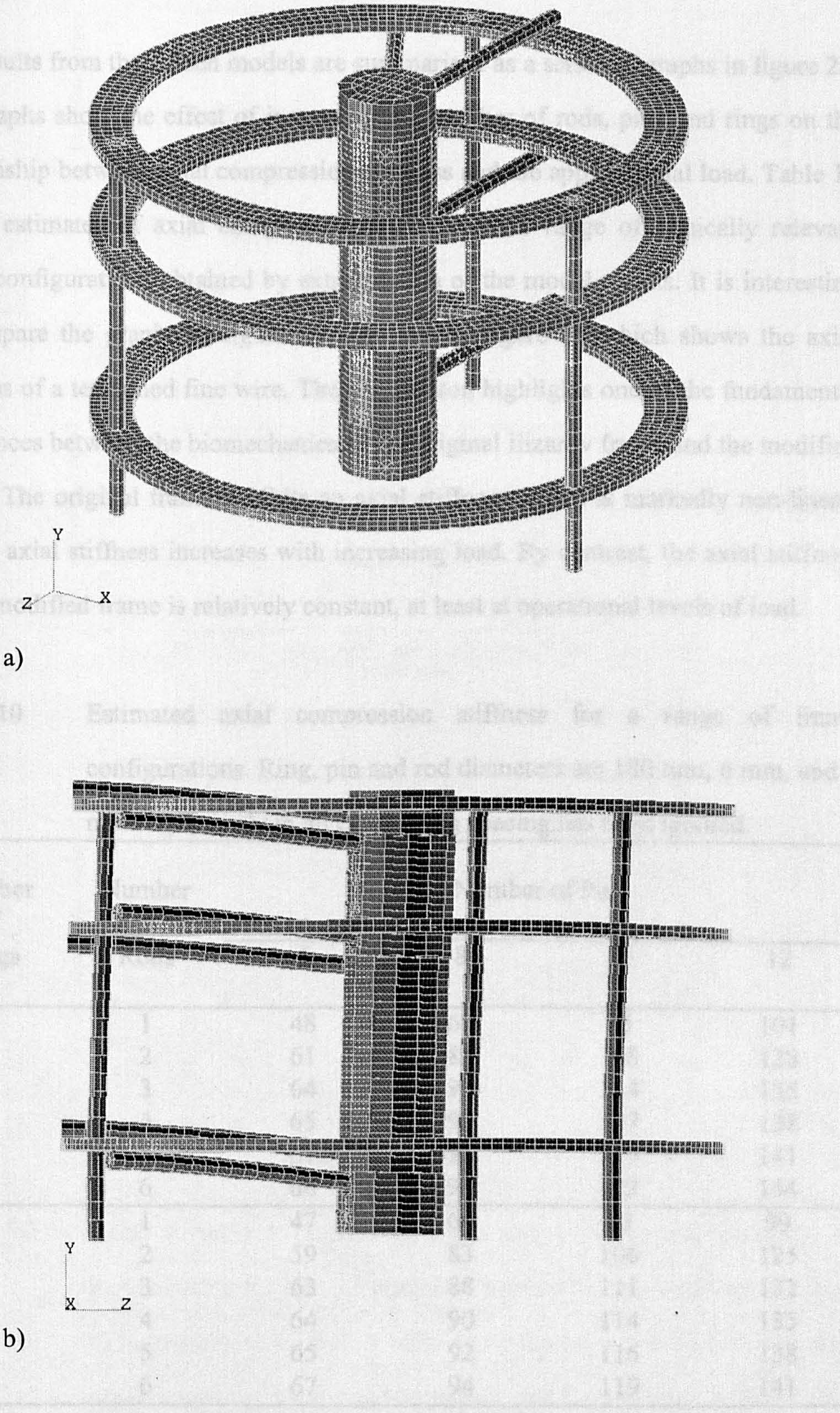


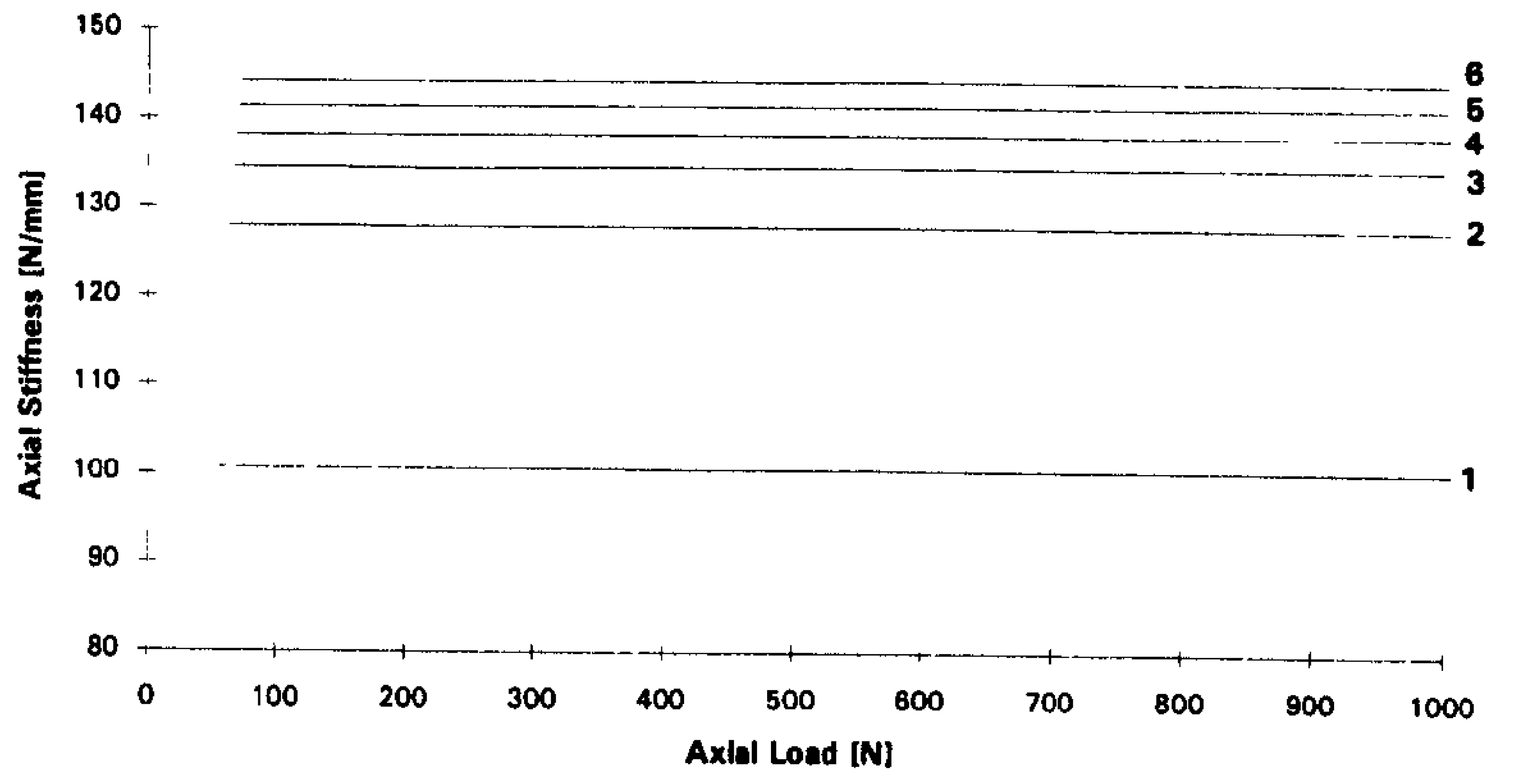
Figure 24 Model 4: a) mesh plot, and b) deformed mesh plot.

3.2.2 Results and Discussion

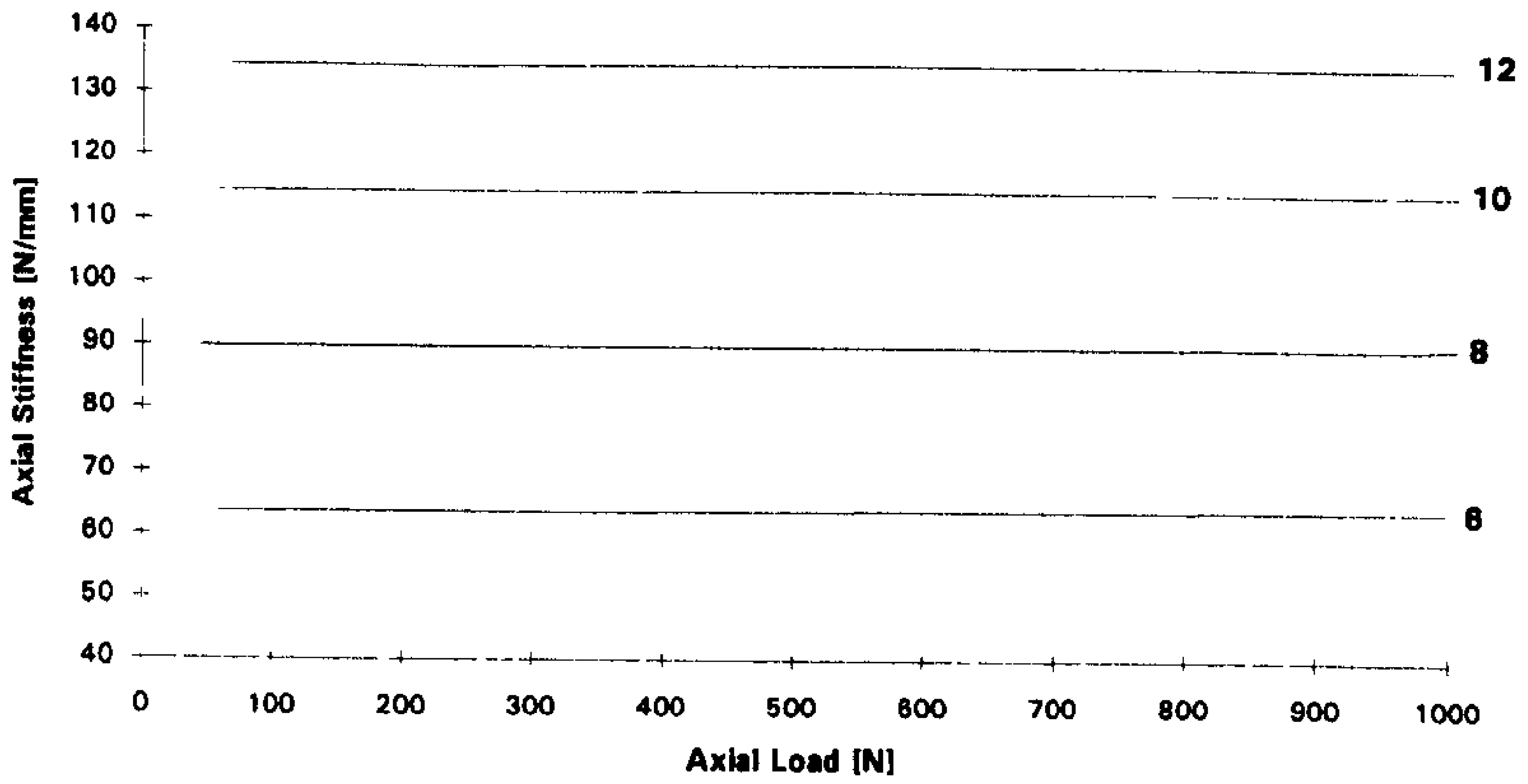
The results from the fifteen models are summarised as a series of graphs in figure 25. The graphs show the effect of increasing the number of rods, pins and rings on the relationship between axial compression stiffness and the applied axial load. Table 10 shows estimates of axial compression stiffness for a range of clinically relevant frame configurations obtained by extrapolation of the model results. It is interesting to compare the graphs in figure 25 with that in figure 15 which shows the axial stiffness of a tensioned fine wire. The comparison highlights one of the fundamental differences between the biomechanics of the original Ilizarov frame and the modified frame. The original frame exhibits an axial stiffness which is markedly non-linear, *i.e.* the axial stiffness increases with increasing load. By contrast, the axial stiffness of the modified frame is relatively constant, at least at operational levels of load.

Table 10 Estimated axial compression stiffness for a range of frame configurations. Ring, pin and rod diameters are 180 mm, 6 mm, and 6 mm respectively in all cases. Ring spacing has been ignored.

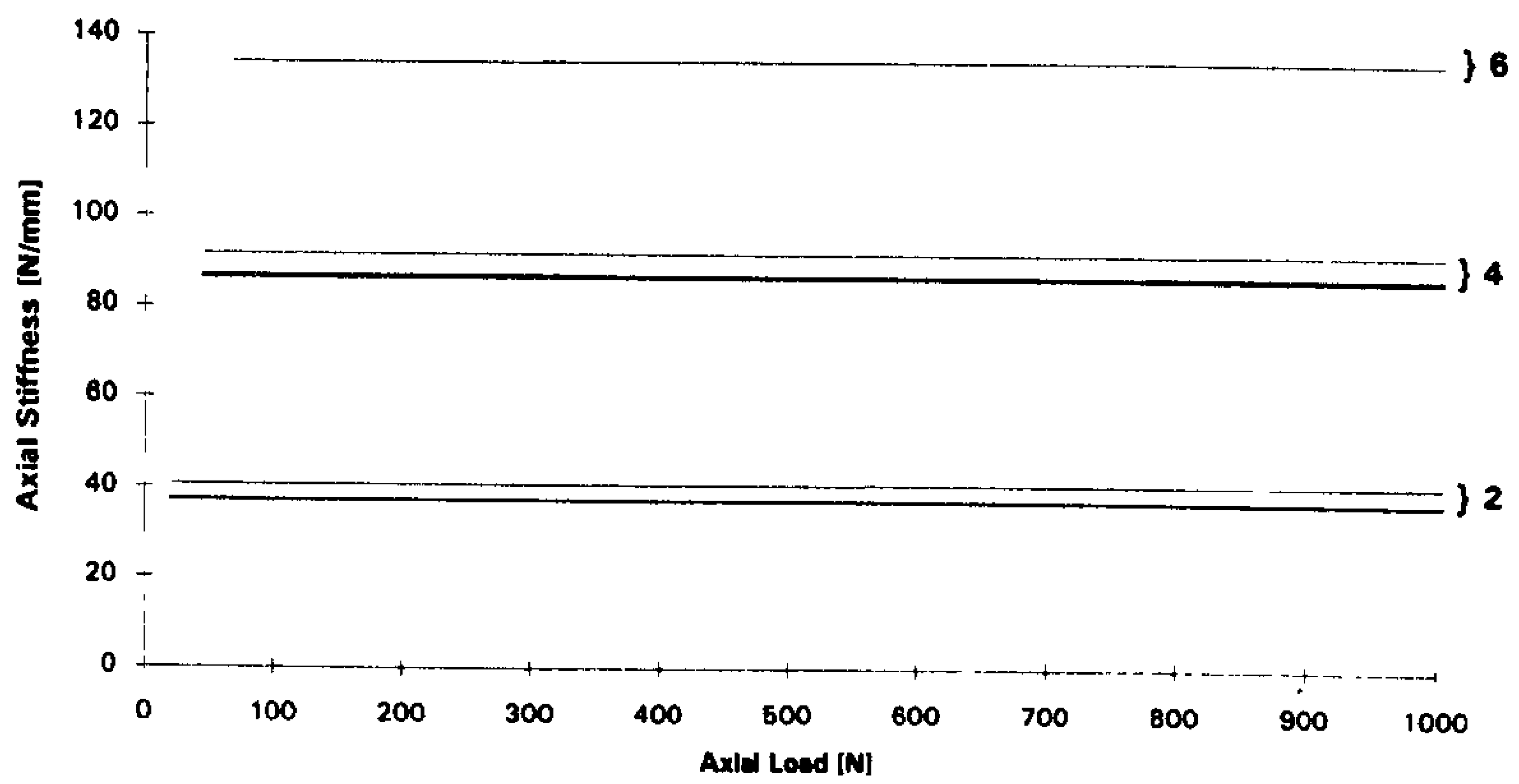
Number of Rings	Number of Rods	Number of Pins			
		6	8	10	12
6	1	48	67	85	101
	2	61	85	108	128
	3	64	90	114	135
	4	65	92	117	138
	5	67	94	119	141
	6	68	96	122	144
4	1	47	66	83	99
	2	59	83	106	125
	3	63	88	111	132
	4	64	90	114	135
	5	65	92	116	138
	6	67	94	119	141



a)



b)



c)

Figure 25 Axial stiffness v. axial load for a range frame configurations: a) incorporating 6 rings, 12 pins, and between 1 and 6 connecting rods, b) incorporating 6 rings, 3 rods, and between 6 and 12 half pins and, c) incorporating 3 rods, and between 1 and 3 rings, each with two pins attached.

Figure 25a shows that as the number of connecting rods increases from 1 to 6, the incremental increase in the overall axial stiffness of the frame decreases significantly; the apparently high value of stiffness for the frame with a single rod was due to the bone ends coming into contact. For example the addition of an extra rod to a single rod frame increases the axial stiffness by 27 %, whereas the difference in stiffness between a 5 rod frame and a 6 rod frame is only 2 %. A similar trend can be seen with the number of pins in figure 25b. Increasing the number of pins from 6 to 8, increases the frame's axial stiffness by 41 %, whereas, adding an additional 2 pins to a 10 pin frame only increases the stiffness by 17 %.

From figure 25c it can be seen that ring spacing *per se*, has a fairly insignificant effect on the axial stiffness of the frame. The difference in axial stiffness between the 2, 4, and 6 ring configurations was largely provided by the extra pins attached to each ring. For example, the difference in stiffness between model 10, which had 4 rings spaced at 30 mm and 100 mm above and below the centre of the fracture gap, and model 11, where the 4 rings were spaced at ± 30 mm and ± 140 mm, was only 0.3 %. The rings are held in place by locking nuts and therefore, they isolate sections of the connecting rod, making them shorter and stiffer. Hence, the axial stiffness of the frame is maximised by equidistant spacing of the rings. In practice they normally are approximately equidistantly spaced, but not necessarily for the above reason.

In clinical practice frames commonly have 4, or 5, connecting rods, 4, or 5, rings, and 8 to 10 pins. A common practice is to de-stabilise the frame once the callus material begins to consolidate. Consolidation of the callus involves the reorganisation of the callus material into more mature bone with a typical lamellar structure. In adult bone the lamellae are orientated approximately parallel to the predominant compressive and tensile stresses to which the bone is subjected. In the diaphysis of a long bone the predominant stresses are approximately orientated with the bone's long axis. From the discussion in section 2, it can be assumed that consolidation would be promoted by the imposition of the normal loading regime, albeit of lower than normal magnitude.

Frames are normally de-stabilised by the removal of 1, or 2, of the connecting rods. From the discussion above it can be seen that this has a relatively small effect on the axial stiffness. However, the removal of rods will probably have a more significant effect on the bending and torsional stiffnesses of the frame. Hence, the axial loads to which the callus is subjected will change little, but the torsional and bending loads may change significantly. Therefore, the mechanical environment imposed on the fracture may be very different from that intended. De-stabilising of frames by the release of one, or more, of the pins would have a greater effect on the axial stiffness and probably a lesser effect on the bending and torsional stiffnesses.

Although no mechanical testing was conducted to validate the finite element analysis as part of this study, the results can be compared with experimental results from a study by Waanders *et al* (97). Waanders conducted mechanical tests on a range of frame configurations to determine their axial stiffness; the frames consisted of four rings with, 2 half pins of 6 mm diameter per ring. The principal objective of the study was to investigate the effect of ring diameter on axial stiffness. Waanders found that when the bone to ring offset was 72.5 mm, *i.e.* that used in the finite element study described above, the average contribution of each half pin to the overall axial stiffness of the frame was 11 N/mm. Unfortunately the number of connecting rods in the frame configuration is not stated, but it can be assumed that between 3 and 5 rods were used, because 4 rod frames are the most usual configuration. A comparison of Waanders' experimental results and the values obtained in the present study are shown in table 11. The results are in reasonable agreement, range 0 to 4.5%, given the simplifications inherent to the finite element model, see section 3.2.1; however, the existence of experimental error in Waanders' study cannot be discounted or quantified.

Table 11 Comparison of experimental and calculated values of the axial compression stiffness of a frame consisting of 4 rings of 180 mm diameter and 8 half pins of 6 mm diameter.

Number of Rods	Waanders *et al.*	Present Study	Difference (%)
3		88	0.0
4	88	90	+2.3
5		92	+4.5

3.2.3 Shear Displacement in Response to an Axial Load

In frames which use full pins, or tensioned fine wires, for the support of bone fragments, such as the original Ilizarov device, axial loads generally produce purely axial displacements. By contrast, in frames which use half pins for the support of bone fragments, such as the modified Ilizarov frame, the displacement of the bone ends in response to an axial load usually has a shear, as well as an axial, component. The shear component arises because the half pins act as cantilevers and the bone fragments rotate about a point defined by the frame configuration. This can lead to shearing of the bone ends, which is generally considered to be deleterious to the healing outcome (39), and a non-uniform stress being applied to the material in the fracture gap. Though obvious, to the present author's knowledge this effect has never commented on in the literature. As it has some interesting implications it will be briefly discussed below.

Figure 26a shows a deformed mesh plot of model 4; a detail of the fracture gap is shown in figure 26b. The applied load causes the bone ends to displace in the Y direction but, because of the effect described above, they are also displaced in the X-Z plane. The direction of the displacement is determined by the frame configuration. If fixation had been by a single pin attached to each ring, the displacement would be towards the pin. In model 4, two pins are used per ring, and so the displacement occurs in the direction of the bisector of the angle between the pins. As the frame modelled is symmetrical about an X-Z plane through the centre of the fracture gap, any two adjacent points on the bone ends, e.g. P and P' in figure 26b, will be displaced by the same amount in the same direction. Hence, there will be no relative displacement between P and P' in the X-Z plane, *i.e.* no shearing of the bone ends will occur.

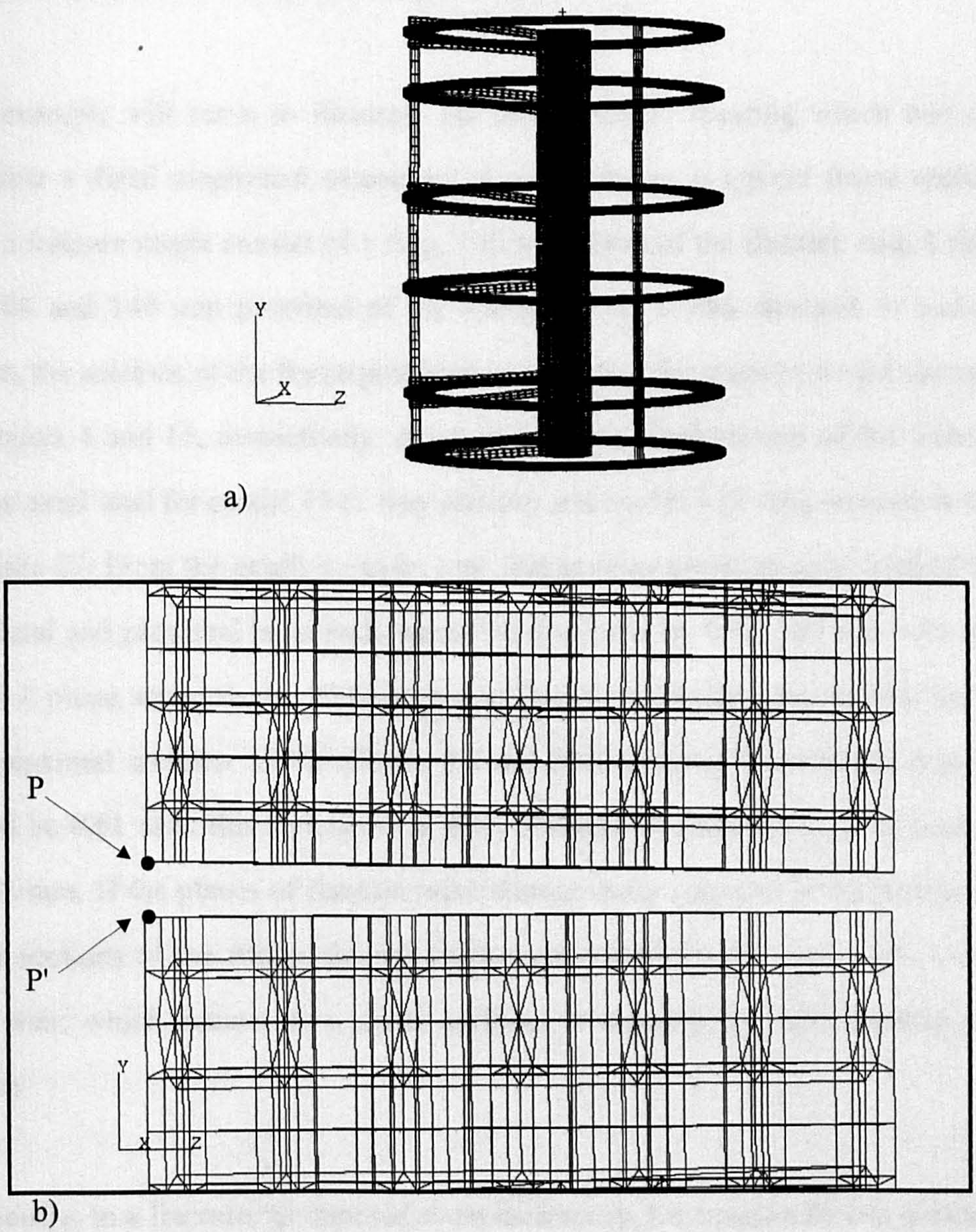


Figure 26 Deformed mesh plots of a of model 4: a) full frame for reference and, b) detail of the region surrounding the fracture gap in a plane bisecting the angle between the pairs of pins.

In clinical practice, the frames applied to mid diaphyseal fractures are generally, reasonably symmetrical about a transverse plane through the centre of the fracture gap, perpendicular to the long axis of the bone. Therefore, shearing of the bone ends in response to axial loads, such as those imposed by functional weight bearing, is likely to be minimal. Conversely, frames applied to proximal, and distal, fractures of the diaphysis tend to be very asymmetric. Therefore, significant shearing of the bone ends during functional weight bearing is likely to occur.

One example will serve to illustrate the magnitude of shearing which can occur. Consider a distal diaphyseal osteotomy in a long bone. A typical frame applied to such a fracture might consist of 1 ring, 140 mm distal of the fracture and, 3 rings at 30, 100 and 140 mm proximal of the fracture, with 2 pins attached to each ring. Hence, the sections of the frame proximal and distal of the fracture would correspond to models 4 and 15, respectively. A graph of shear displacement of the bone ends versus axial load for model 15 (1 ring section) and model 4 (3 ring section) is shown in figure 27. From the graph it can be seen that in response to an axial load of 200 N the distal and proximal bone ends would be displaced by 0.92 mm and 0.31 mm in the X-Z plane, respectively. If the planes of fixation were the same in both the distal and proximal sections of the frame, the net displacement between the bone ends would be 0.61 mm; this equates to a shear stiffness in response to axial loading of 328 N/mm. If the planes of fixation were diametrically opposed in the proximal and distal sections of the frame, the net displacement between the bone ends would be 1.23 mm; which equates to a shear stiffness in response to axial loading of 163 N/mm.

Obviously, in a fracture, as opposed to an osteotomy, the magnitude and direction of any displacement that occurs will be significantly influenced by the geometry of the fracture. A well reduced fracture with a saw-tooth profile, for instance, might be very stable, though the teeth would be subject to significant transverse stress. It also worth noting that shearing of the bone ends can be minimised, or eliminated, by optimising the radial spacing of the half pins. This is obviously only possible in circular frames and may be precluded by other considerations, such as soft tissue transfixion. In the tibia, for example, half pins are normally only inserted into a "safe zone" in the anterior-medial quadrant where the soft tissue cover is minimal and there are no important neurovascular structures.

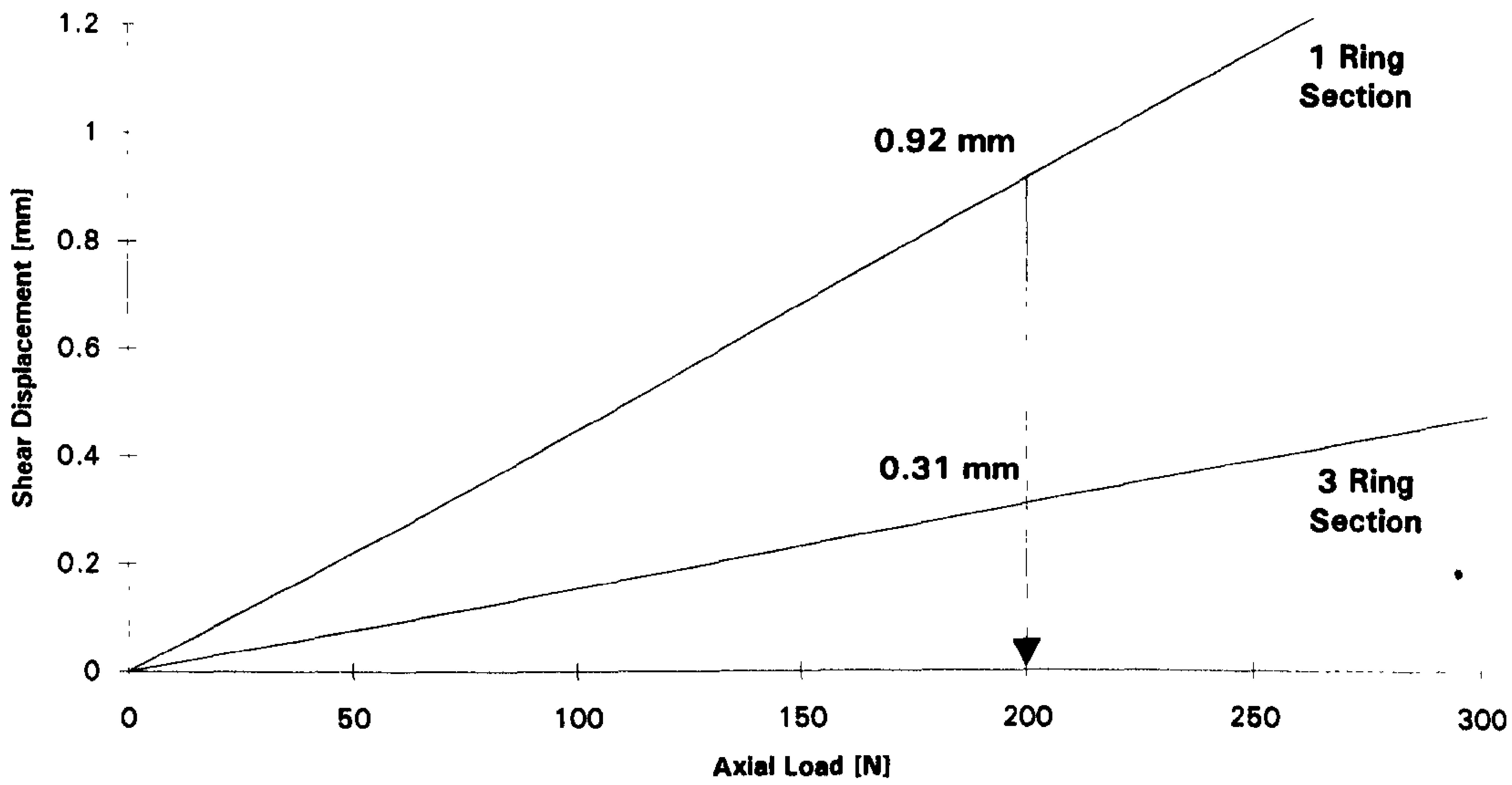


Figure 27 Shear displacement of the bone ends versus axial load for model 15 (1 ring section) and model 4 (3 ring section).

Another significant aspect of the mechanical behaviour of frames in which half pins are used to support bone fragments, is that under axial compression a non-uniform stress is usually imposed on material in the fracture gap, or the bone ends themselves if they come into contact. This arises because the axial displacement, *i.e.* displacement in the Y direction in the model considered, is non-uniform due to rotation of the bone fragments. This can be seen in figure 26b where the fracture gap varies in magnitude from a maximum between P and P', to a minimum on the opposite side. In general, the region of highest stress will be found diametrically opposite the plane of fixation, if only one plane of fixation is applied, and diametrically opposite the bisector of the angle between the planes of fixation, if two are used.

An illustration of the possible clinical consequences of the effect described above is provided by patient T6. The patient had a severe compound fracture of the left tibia which was treated with a bone graft and eventually united. Apparently, the grafted section did not remodel properly because several years later the bone refractured with minimal trauma. A section of bone was resected, the bone ends were squared off and approximated, and a frame applied, figure 28. The frame consisted of 2 rings distal of the fracture, and 2 rings proximal of the fracture; all approximately equidistant. Fixation was by 2 olive wires in the proximal ring and 2 half pins in each of the other rings; fixation planes were approximately anterior-posterior and medial-lateral. As the frame was approximately symmetrical about a plane parallel to and through the centre of the osteotomy gap it can be assumed that shearing of the bone ends was minimal. From the discussion above, the region of highest stress can be predicted to be in the posterior-lateral quadrant of the bone ends.

7 weeks after application of the frame radiographs showed that callus material was beginning to form in the posterior-laterial quadrant. By 31 weeks after frame application, when the clinical study finished, the callus in this quadrant had developed into a buttress of new bone but callus material had not yet formed in any of the other three quadrants. Whilst the slow healing of this fracture cannot be unequivocally attributed to a cyclic non-uniform stress being imposed on the osteotomy gap during functional weight bearing, it seems probable that the non-uniform stress was at least a contributory factor.

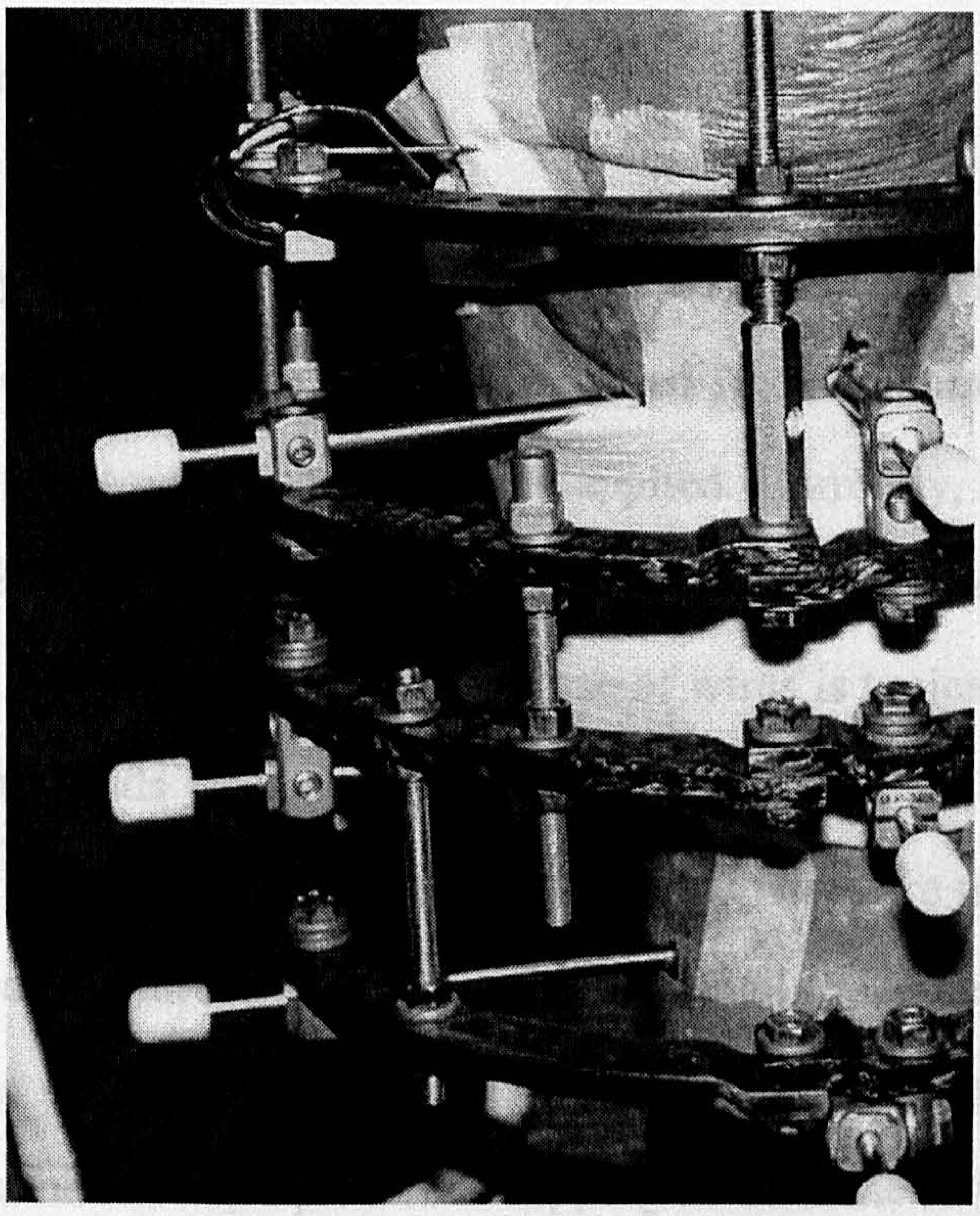


Figure 28 Photograph of the frame applied to the left tibia of patient T6.

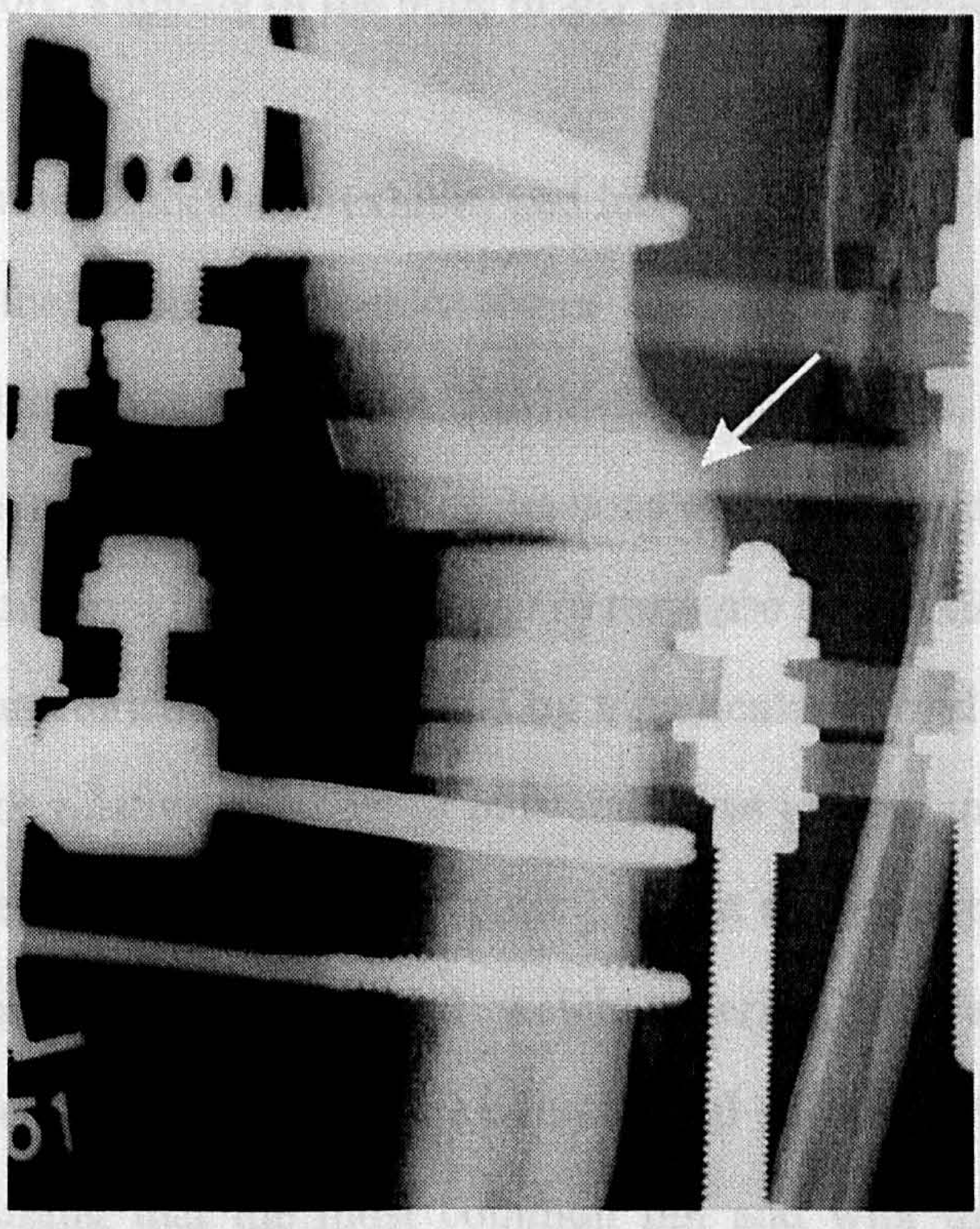


Figure 29 Anterior-posterior radiograph of patient T6 31 weeks after frame application. A buttress of new bone in the posterior-lateral quadrant is indicated by the arrow.

3.3 The Hybrid Ilizarov Frame

At the Bristol Royal Infirmary, both original Ilizarov frames, which use tensioned fine wires to support bone fragments, and modified Ilizarov frames, which use half pins to support bone fragments, are routinely applied. Currently, however, the most commonly applied type of frame is the hybrid frame in which a combination of pins and wires is used. In these hybrid frames the use of wires is typically confined to the distal and proximal ends of the tibia, and the distal end of the femur, where transfixion of soft tissues is minimal. Generally, olive wires are used, as opposed to plain wires. As manufactured, olive wires have a small, bead shaped protuberance about a third of the distance from one end. When the wires are inserted the olive is approximated with the bone and precludes slipping of the bone in the direction of the olive. The wires are generally inserted in mutually perpendicular pairs, or even in groups of 3, therefore, slipping of the bone in any direction is excluded.

Hybrid frames can be expected to exhibit, and have been shown to exhibit (**33, 96**), characteristics of the mechanical behaviour of both the original and the modified Ilizarov frame. Hence, they will have a non-linear axial stiffness, and, depending on their configuration, may cause shearing of the bone ends and the imposition of a non-uniform stress on material in the fracture gap in response to an axial load. The degree to which these characteristics are exhibited by a particular hybrid configuration will be dependent on the relative numbers of pins and wires present in the configuration, all other factors being equal. It is worth noting that at moderate to high axial loads, such as those imposed by functional weight bearing, the average individual contributions of each pin and wire to the overall axial stiffness of the frame may be very similar, assuming that the most common pin and wire diameters, and wire pretensions are used. A final point worth noting, is that hybrid frames, like the original frame, are likely to display a gradual loss in stiffness due to yielding of the fine wires in response to functional weight bearing.

CHAPTER 4. Mechanical Monitoring of Fracture Healing

The objective of the study described in this section, and section 5, was to investigate techniques to a) measure the absolute stiffness of a healing fracture and b) monitor the increase in relative stiffness of a fracture as healing progresses with a circular external frame *in-situ*. Relevant previous studies will be briefly reviewed in section 4.1. The validity of using fracture stiffness measurements as an indicator of fracture healing and strength has generally been assumed in these studies. This is obviously a fundamental assumption, and so its validity will be briefly discussed in section 4.2. *In-vitro* tests of techniques of absolute stiffness measurement and relative stiffness measurement will then be described in sections 4.3 and 4.4, respectively. The outcomes of these tests will be discussed in section 4.5 and an *in-vivo* trial of one of the relative stiffness monitoring techniques will be described in section 5.

4.1 Previous Studies

Various methods of monitoring fracture healing by measuring deformation of the fracture-external frame system have been developed in both *in-vitro* and *in-vivo* studies for unilateral and bilateral frames; these will be discussed below. All these techniques have shared the same principle, *i.e.* that the fracture can be considered as a structural member of variable stiffness in parallel with the external fixator. Initially, the fracture is incapable of carrying all of the applied load. Therefore, a proportion of the load is transmitted through the frame, inducing strain in the connecting rods and deflecting the pins. The exact proportion of the load which can be carried by the fracture is determined largely by the geometry of the fracture. An oblique fracture, for example, will be able to carry very little axial load. As the fracture heals the proportion of the load it is able to carry increases. Hence the strain in the rods and deflection of the pins reduce. By taking initial measurements of the strain and/ or deflection and relating these to subsequent measurements taken under the same loading conditions, the degree of healing can be monitored.

The theory described above has been verified *in-vitro* by Bourgois and Burny in an study using an excised cadaveric tibiofibular assembly (**101**). The tibiofibular assembly was mounted in a rig which allowed compressive loads to be applied to it, and strain gauges were bonded to the surface of the tibia. A uniaxial fixator, which had strain gauges bonded to the surface of its connecting rod, was then applied to the tibia. Tibial strain, as recorded by the strain gauges bonded to its surface, dropped by 20 % on application of the fixator. An osteotomy was then created in the fibula and the cortex of the tibia was thinned in 6 stages by a series of symmetrical cuts, *i.e.* at each of the 6 stages the distribution of the uncut bone remained in proportion to the intact bone. In a final stage the osteotomy was completed. At each stage connecting rod strain was seen to rise in proportion to the drop in tibial strain.

There have been several *in-vivo* studies in which fracture healing has been monitored by monitoring the deformation of uniaxial fixators. Strain gauges bonded to the connecting rod of a fixator have been used to monitor fractures of the neck of the humerus (**57**). Loading of the fixator, in this case, was achieved by the horizontal extension of the arm; the resultant bending strain induced in the connecting rod by the effects of gravity was measured. Removable strain gauged transducers have been used to measure strain induced in the connecting rod of tibial fixators by axial and bending loads (**52, 59, 60, 75, 76**). Other studies have used dial micrometers (**58**) and conductive plastic displacement transducers (**61**) to measure deflection of the half pins, in response to axial loading, in tibial and femoral fixators.

Studies involving the use of finite element analysis and *in-vitro* mechanical tests have shown that pin deflection and connecting rod strain, in response to an axial load, can be used to predict the stiffness of material in the fracture gap under conditions of Hoffmann-Vidal biaxial fixation (**77, 102**). *In-vivo* applications of the theory described above in biaxial fixation include the use of bonded strain gauges to monitor strain induced in the connecting rods by axial and bending loads (**78**)

Relatively few studies have attempted to monitor fracture healing under conditions of Ilizarov fixation; possibly this reflects the greater geometrical complexity of circular frames over other types of fixator. One *in-vivo* study involved the use of strain gauges bonded to the fixation wires to monitor strain induced by axial loading (**103**). It is not clear how such an approach can be successful, given that plastic deformation of the wires will occur, as described in section 3.1. The only major study was a multi-centre trial in Italy, which involved the use of a removable extensometer and a variety of axial, bending, and torsional loading regimes (**104-106**). This second study will be considered in more detail in section 4.4.

Only in a few of these studies was an attempt made to determine absolute values of fracture stiffness (**59, 60, 75, 76**). This was achieved by determining the stiffness characteristics of the fixator, uniaxial fixators of simple configuration, and back-calculating. In the other studies bone healing curves were generated based on the measurements of deformation as a function of time. It has been shown *in-vitro* that such curves will asymptote to a final value when the stiffness of the fracture reaches 25 % that of intact bone (**102**). Another study showed by theoretical analysis of the Hoffmann-Vidal biaxial fixator, that the curves tended to a value when the strength of the fracture reached 50 % that of intact bone (**78**). To allow the strength and stiffness of the new bone to increase further it is then necessary to remove the external fixator so that normal bone remodelling can occur (**76**). In one study relative deformation was used as a direct measure to make comparisons between patients and as a prognostic tool (**57**).

An obvious problem with these techniques is that the stiffness of the fixator is assumed to remain constant throughout the monitoring period. Failure of any of the frame components will reduce the stiffness of the frame and, therefore, may compromise the validity of any subsequent measurements. Pin loosening is the most common mode of failure in fixators in which pins are used to support bone fragments. In a study using a finite element model to simulate a monitoring system for a biaxial fixator, failure of one of six pins was found to alter the connecting rod strain by 15-25%, whereas pin deflection was found to alter by only 0.5-1% (**102**). Hence, techniques involving the measurement of pin deflection may be more suitable for long-term monitoring, in such fixators, than those involving the measurement of connecting rod strain. In frames in which fine tensioned wires are used for support, the most common mode of failure is plastic deformation of the wires leading to a drop in wire tension and, hence, frame stiffness. The effect of such failure on connecting rod strain is likely to be less significant in axial loading.

In the case of uniaxial fixation a technique of directly measuring the bending stiffness of the healing fracture is available which is virtually independent of assumptions about the structural integrity of the fixator (**52, 107**). The technique involves temporarily removing the connecting rod of the fixator and replacing it with an electrogoniometer. A load can then be applied and the fracture stiffness measured directly. The goniometers used for this purpose have a very low stiffness and so allow valid measurements to be made even if the pins are loose because the loads transmitted across the screws are small. In fact, the technique has even been applied to conservatively managed fractures where the goniometer was held in place by orthoplast straps; apparently with no slippage, and with reasonable results (**108**).

4.2 Axial and Bending Stiffness as Indicators of Fracture Healing

In the majority of the studies in which observation of the deformation of the fracture-external frame system has been used to assess fracture stiffness, a greater emphasis has been placed on determining the bending stiffness of the fracture than its axial stiffness; there are two main reasons for this. Firstly, as originally conceived, such techniques were intended as a substitute for the estimation of fracture stiffness by the physical manipulation of the limb, which is obviously not possible with the frame *in-situ*. Estimating the bending stiffness of a diaphyseal fracture by physical manipulation is far easier than estimating its axial stiffness. Secondly, in inherently stable fractures, such as transverse fractures, a greater proportion of the load applied to the fracture-external frame system is transmitted to the frame in bending than in axial loading. Neither of these reasons implies that bending stiffness is a better indicator that normal healing is progressing, or of the strength of the fracture, than axial stiffness. The relative merits of the bending stiffness and the axial stiffness of fractures as indicators will be briefly considered below.

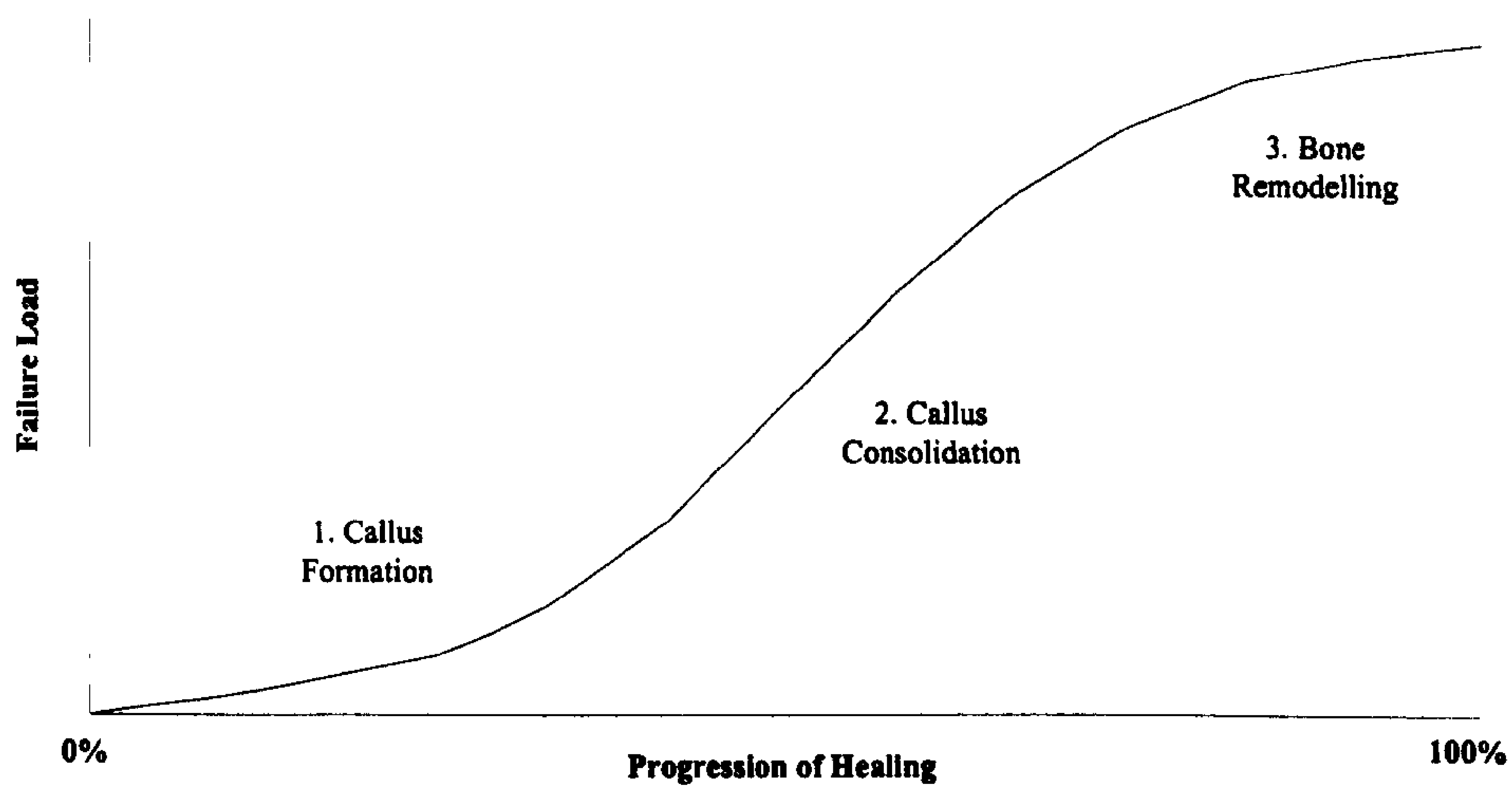


Figure 30 The triphasic relationship between fracture tensile strength and the progression of healing, abscissa not to scale. After Prat *et al.* (109).

The relationship between the tensile strength of a healing fracture and the progression of fracture healing is triphasic, the phases correspond to the major stages in the healing process (109). Initially, a fracture has zero strength, at least in tension. Callus material then begins to form in the fracture gap and the strength of the fracture gradually increases. This immature callus material is composed of woven bone in which there is no differentiation of the bundles of collagen fibres and CHA crystals, *i.e.* their orientation as a whole is independent of applied stress and their individual orientation appears random.

Once the fracture gap has been bridged and sufficient callus has formed to reduce high levels of strain induced by functional loading, the callus consolidates. Consolidation of the callus material involves the organisation and remodelling of the woven bone into more mature bone with a lamellar structure in which the fibre/CHA bundles are aligned parallel with predominant compressive and tensile stresses. During consolidation the strength of the fracture rapidly increases and once the callus has consolidated additional stabilisation is unnecessary. The final stage involves the remodelling of the bone into something like its original, pre-fracture, state and takes place relatively slowly, leading to a final gradual rise in the strength of the fracture.

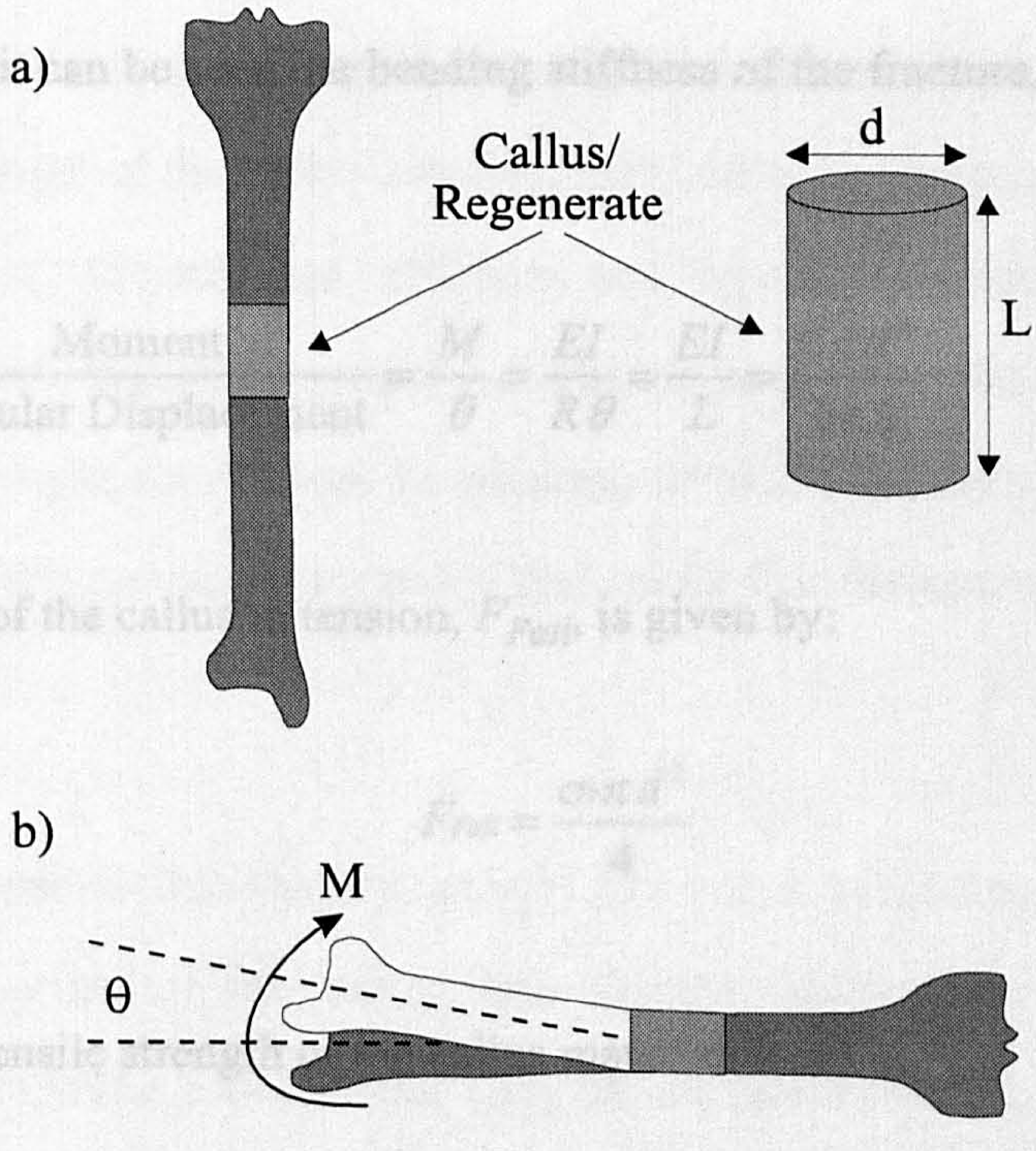


Figure 31 Fracture stiffness measurement: a) fracture model as a cylinder of callus/regenerate of length, L, and diameter, d, and, b) an applied moment, *M*, produces an angular deflection of θ.

The callus, or segment of maturing regenerate, can be considered as a cylinder, figure 31a. The length, L, of the cylinder will be maintained at a constant average value by the fixator if shortening of the limb is to be avoided. The Young's modulus, E, strength, σ, and diameter, d, of the callus will change as healing progresses. The Young's modulus varies from 500 kPa for granulation tissue, the precursor of early callus, to as much as 20 GPa for mature bone (**110**). Therefore, during the early stages of healing at least, all deformation can be assumed to occur in the callus.

The axial stiffness of the fracture, k_A, is given by:

$$k_A = \frac{\text{Force}}{\text{Displacement}} = \frac{\sigma \pi d^2 / 4}{\varepsilon L} = \frac{E \pi d^2}{4L} \qquad (1)$$

From figure 31b it can be seen the bending stiffness of the fracture, k_B, will be given by:

$$k_B = \frac{\text{Moment}}{\text{Angular Displacement}} = \frac{M}{\theta} = \frac{EI}{R\theta} = \frac{EI}{L} = \frac{E\pi d^4}{64L} \qquad (2)$$

The failure load of the callus in tension, F_{Fail}, is given by:

$$F_{Fail} = \frac{\sigma_T \pi d^2}{4} \qquad (3)$$

where σ_T is the tensile strength of the callus material.

The bending moment which will cause the callus to fail, M_{Fail}, is given by:

$$M_{Fail} = \frac{EI}{R_{Fail}} = \frac{\sigma_T I}{y} = \frac{\sigma_T \pi d^4 / 64}{d/2} = \frac{\sigma_T \pi d^3}{32} \qquad (4)$$

From equations (1) and (3), it can be seen that the axial stiffness and strength are both proportional to diameter^2. By comparison, from equations (2) and (4), it can be seen that bending stiffness is proportional to diameter^4, yet bending strength is proportional to diameter^3. Hence, the ratio of axial strength to axial stiffness is independent of the diameter, *i.e.* axial stiffness and strength will increase by equal multiples as the diameter increases. The ratio of bending strength to bending stiffness, however, is dependent on 1/diameter, thus bending stiffness increases more rapidly than bending strength as the diameter increases. Axial and bending stiffness are also both proportional to the Young's modulus, *E*, and *1/L*; axial and bending strength are both proportional to tensile strength, σ_T. Of the quantities in equations (1) to (4), the Young's modulus, *E*, diameter, *d*, and the tensile strength of the callus material, σ_T, can be considered as variables during the progression of fracture healing.

During callus formation the diameter of the callus will increase, as will the Young's modulus and strength of the callus material. Early callus is composed of woven bone with a minimally differentiated structure and can be considered to relatively isotropic. Therefore, though no proportionality can be assumed between the Young's modulus and strength, an increase in bending, or axial, stiffness will indicate that fracture healing is progressing normally, and imply that the strength of the fracture has increased.

During callus consolidation the diameter of the callus will be maintained, but the mechanical properties of the callus will change because the woven bone is remodelled into lamellar bone. Unlike early callus, mature callus, like mature bone, has a highly differentiated structure and is highly anisotropic. The Young's modulus of mature human cortical bone is typically of the order of 20 GPa in the direction parallel to the lamellae and 12 GPa perpendicular to the lamellae (111). Strength displays similar directional differences. The compressive strength of human cortical bone is typically of the order of 200 MPa in a direction parallel to the lamellae but only 140 MPa perpendicular to the lamellae; parallel and perpendicular tensile strengths of 140 MPa and 10 MPa, respectively, are typical (99).

Given the degree of anisotropy that develops in the callus material during consolidation, a loss of proportionality between bending stiffness and axial stiffness seems likely at this stage in the healing process. Furthermore, either property, or both, might be expected to become a poor indicator of fracture healing, and strength, as consolidation of the callus and bone remodelling progresses. However, the results of a couple of animal studies suggest that both can be used as indicators of fracture healing, but that axial stiffness may be a better indicator of strength than bending stiffness in the later stages of healing. These studies will be considered briefly below.

One of the studies used a tibial osteotomy in sheep as a fracture model (**53**). The sheep had a external fixator attached to both tibia; a 2 mm osteotomy was made in the left tibia. The sheep were then culled at 2, 4, 6, 8, or 10 weeks; and both tibiae harvested. The stiffness and strength of the osteotomised and control tibiae were then compared in four-point bending. The study found a biphasic relationship between bending stiffness and strength. At lower bending stiffness values there was a strong correlation between stiffness and strength, with a coefficient of correlation, r, of 0.89. At higher stiffness values, there was no significant correlation, with r equal to 0.00. The study found that the second phase, *i.e.* that in which there was no correlation, started when the stiffness reached approximately 65 % of the normal stiffness. This is an important result because studies in human tibiae have shown that fixation can be removed without risk of refracture when the bending stiffness reaches 25 % that of an intact tibia (**52, 107**).

The second study used a closed femoral fracture in rats as a fracture model (**112**). The study was primarily an investigation of the effects of osteoporosis on fracture healing but results from the control group can be used to draw more general conclusions. The rats had a Kirchner wire introduced into the medullary canal of their right femur; a fracture was then made using a three-point bending jig. The animals were culled at 2, 4, or 6 weeks; the femora were then harvested and divided into 2 random groups. In one group the tensile stiffness and tensile strength of the healing fractures was determined; in the other, the bending stiffness and strength in four-point bending were determined. Samples of the callus material were then examined histologically; at 2 weeks callus had formed, at 4 weeks the callus had consolidated, and by at 6 weeks the bone had been remodelled. Results from the control group in the study have been extracted and are shown in table 12. Values of bending stiffness, tensile stiffness, ultimate tensile strength, and ultimate bending strength, for the 2 and 4 week cohorts have been expressed as ratios of the 6 week cohort values by the present author. These ratios indicate that at the onset of callus consolidation, *i.e.* week 2, both bending and tensile stiffnesses were reasonable indicators of fracture strength. By the end of callus consolidation, or the onset of bone remodelling, *i.e.* week 4, tensile stiffness was a better indicator of strength than bending stiffness, which would significantly have overestimated both the tensile strength and the bending strength.

Table 12 Mean mechanical properties of fractures in healing rat femora expressed as ratios of the mean properties of healed fractures. Data from Walsh, W.R. *et al.* (**112**).

Weeks Post-Fracture	Bending Stiffness Ratio	Tensile Stiffness Ratio	Tensile Strength Ratio	Bending Strength Ratio
2	0.14	0.14	0.16	0.16
4	0.98	0.62	0.32	0.68

There are two main objectives for making fracture stiffness measurements in fractures managed with external fixation *viz.*; to ensure that healing is progressing normally and to determine the point when fixation may be removed without risk of refracture. From the above discussion, it can be concluded that both fracture bending stiffness and fracture axial stiffness can be used to achieve these objectives. However, in the later stages of healing, tensile axial stiffness may be a better indicator of fracture strength. This is probably due to the anisotropic nature of mature callus and bone.

4.3 Absolute Stiffness Measurement

In this section a technique which could potentially be used to estimate the strength of a healing fracture by measurement of its tensile stiffness will be discussed; there were two main reasons for basing the technique on the tensile stiffness of the fracture rather than its bending stiffness. Firstly, in section 4.2 it was concluded that, on available evidence, the tensile axial stiffness of a fracture, or segment of regenerate, is likely to provide a better indicator of fracture strength throughout the progression of fracture healing, than its bending stiffness. Therefore, it would seem desirable that any technique to estimate the strength of a healing fracture by inference from its stiffness characteristics, should draw the inference from the fracture's tensile stiffness, rather than its bending stiffness. Secondly, in practice, under conditions of Ilizarov fixation it is far easier to apply a tensile load to the fracture, or section of regenerate, than a bending load. Indeed, one of the design tenets of the Ilizarov frame was that it should allow bone fragments to be displaced axially, during distraction osteogenesis, for example. Additionally, small axial displacements should have little effect on the integrity of healing fractures, or sections of consolidating regenerate, because both can tolerate quite high levels of tensile axial strain without damage.

In concept, the technique is very simple. A small tensile axial load is applied to the bone either side of the healing fracture, or section of consolidating regenerate, via the frame components connected to it and the resulting displacement measured. In practice, as part of the frame, healthy bone material, the callus material, and/or regenerate material, are in series, the ratio of the applied load to resultant displacement will give the combined stiffness of the system. Therefore, it will be necessary to take a zero reading shortly after frame application, when the fracture can be assumed to have nominal stiffness, to allow the contribution of the frame and soft tissues to the overall stiffness to be assessed. This value can then be deducted from subsequent measurements to yield the stiffness of the mature bone-fracture/regenerate-mature bone system between the fixation points distal and proximal of the fracture. As the value of the Young's modulus of the callus/regenerate material is considerably lower than that of the mature bone, the majority of deformation can be assumed to occur in the callus/regenerate material.

Hence, the fracture stiffness can be assumed to be approximately equal to the stiffness of the mature bone-fracture-mature bone system.

As has been mentioned above, each Ilizarov frame has a unique configuration; factors such as ring spacing, and the relative numbers of components used, vary widely. To ensure the widest possible applicability of the technique, two different methods were devised to measure stiffness; each method used a slightly different set of transducers. The methods differed principally in the manner in which the tensile load was measured; they will be referred to as the force washer method and the force bolt method. In each case a range of connectors was designed and fabricated which allowed the relevant transducers to be attached to the frames in a variety of ways, e.g. in-line with the rings, exterior to the frame, etc.

In both methods, the basic technique involves loosening the connecting rod nuts on one side of a ring adjacent to the fracture, or section of regenerate. This allows the ring to move relative to the adjacent ring by a controlled amount in an axial direction. A tensile load is then applied between this ring and the adjacent ring by means of a screw jack. In one method, the load is then measured by a force bolt transducer mounted above, or below, the displaced ring; in the other the load is measured by a force washer transducer located between the jack and the ring. In both methods, the resulting displacement is measured by a linear variable-differential transformer, l.v.d.t.. The configuration of the instrumentation for the force bolt method is shown in figure 32; figure 33 shows the force washer method configuration. In practice, it is necessary to use three or four sets of instrumentation to ensure the ring moves in a purely axial manner; the readings are averaged to calculate the axial stiffness.

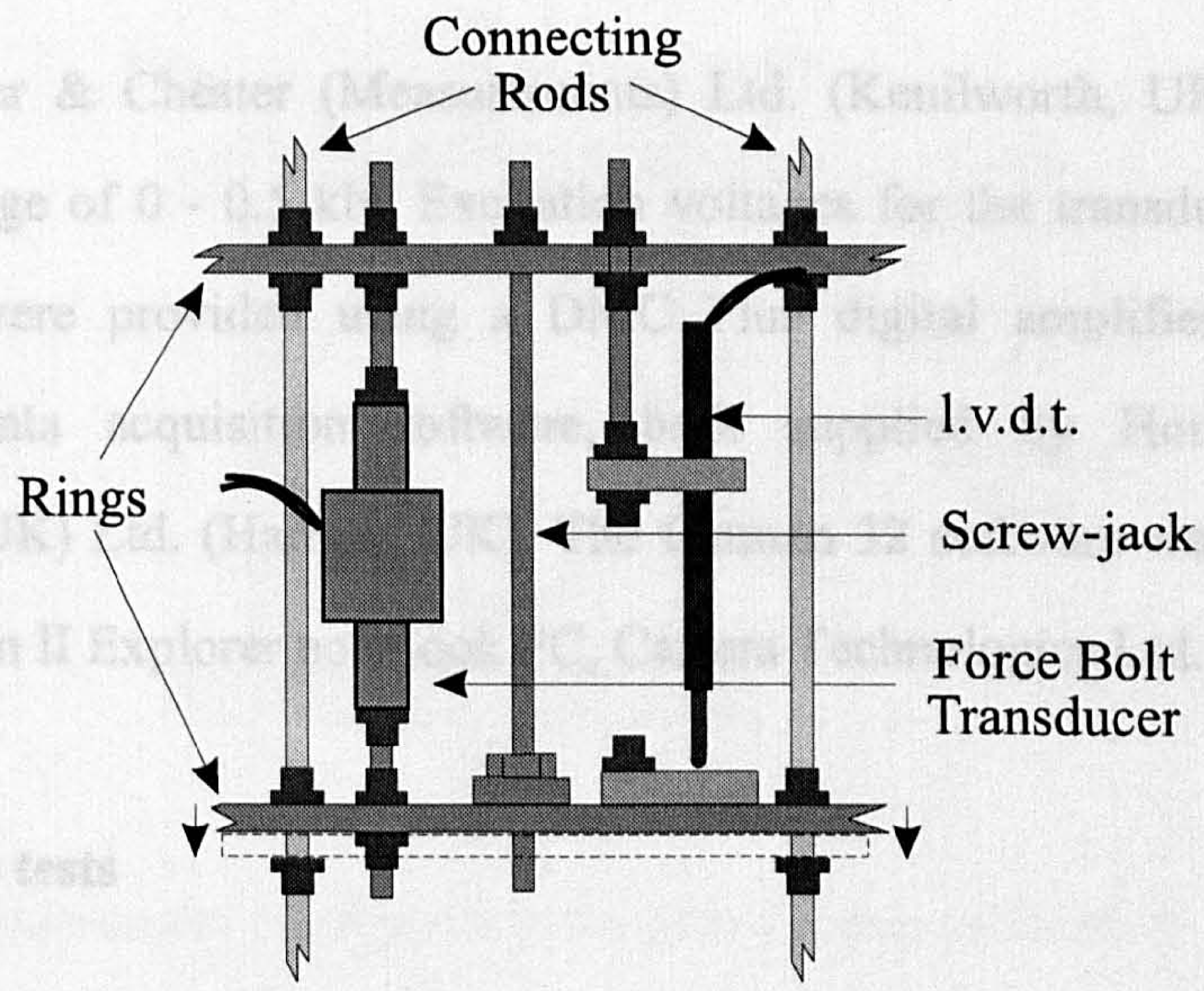


Figure 32 Tensile stiffness measurement: configuration of instrumentation for the force bolt method.

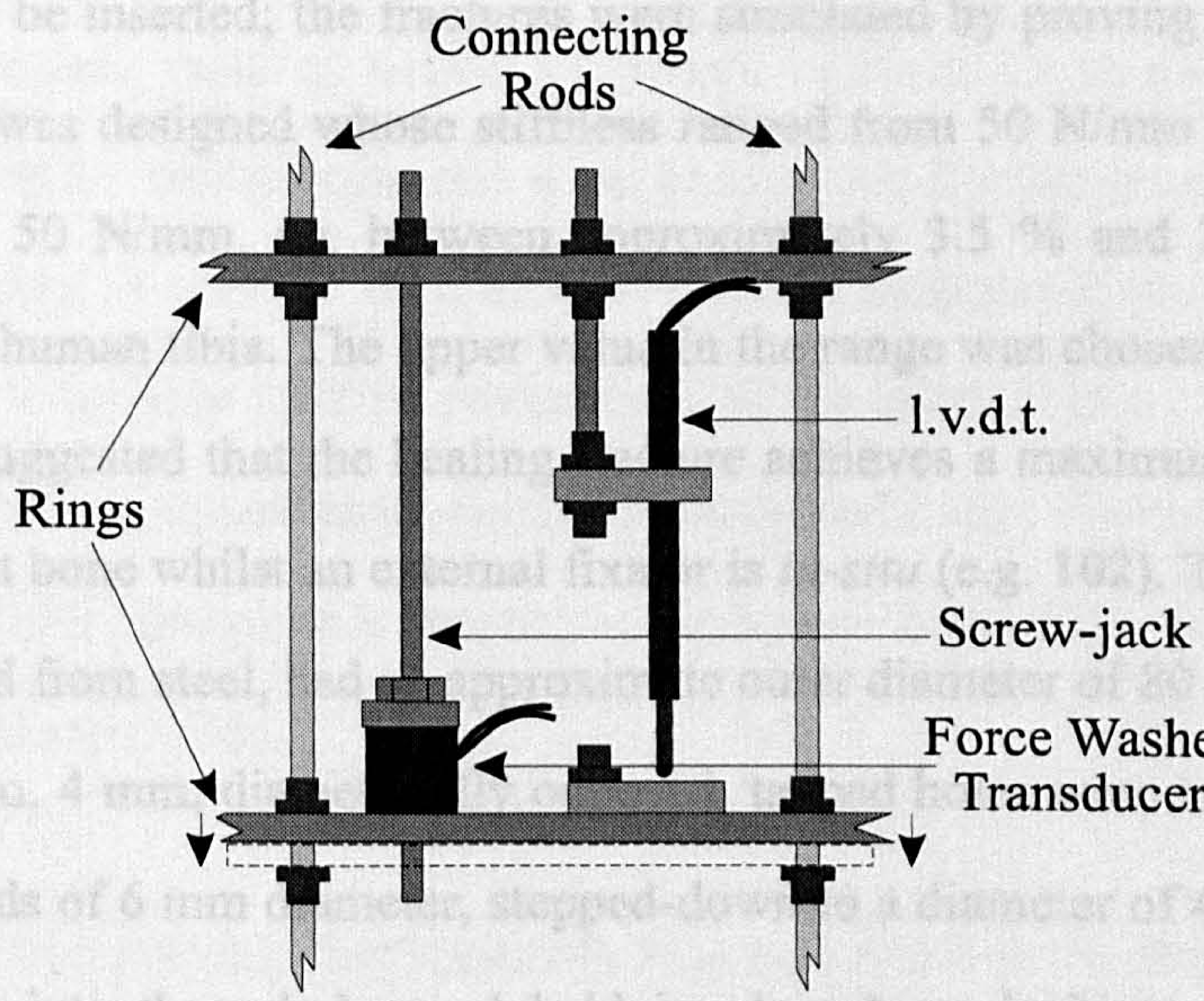


Figure 33 Tensile stiffness measurement: configuration of instrumentation for the force washer method.

The transducers required for the two methods consist of: force washer transducers, force bolt transducers, and linear variable-differential transformers. U9B force bolts and W5TK-2 l.v.d.t. displacement probes were supplied by Hottinger Baldwin Messtechnik (UK) Ltd. (Harrow, UK); the U9Bs have an operational range of 0 - 2 kN, the probes have a stroke of ±5 mm. The force washer transducers were custom-built by Procter & Chester (Measurements) Ltd. (Kenilworth, UK) and have an operational range of 0 - 0.5 kN. Excitation voltages for the transducers and signal conditioning were provided using a DMC Plus digital amplifier controlled by Catman 32 data acquisition software, both supplied by Hottinger Baldwin Messtechnik (UK) Ltd. (Harrow, UK). The Catman 32 software was mounted on a Carrera Pentium II Explorer notebook PC, Carrera Technologies Ltd. (London, UK).

4.3.1 *In-vitro* tests

The test rig for the tensile stiffness measurement technique consisted of a modified Ilizarov frame, of typical configuration, into which simulated fractures of a range of stiffness could be inserted; the fractures were simulated by proving rings. A set of 7 proving rings was designed whose stiffness ranged from 50 N/mm to 350 N/mm in increments of 50 N/mm, *i.e.* between approximately 3.5 % and 25 % that of an average intact human tibia. The upper value in the range was chosen because several studies have suggested that the healing fracture achieves a maximum stiffness of 25 % that of intact bone whilst an external fixator is *in-situ* (e.g. **102**). The proving rings were fabricated from steel, had an approximate outer diameter of 80 mm and a length of 10 mm. Two, 4 mm, diametrically opposed, tapped holes were made in the rings. Connecting rods of 6 mm diameter, stepped-down to a diameter of 4 mm at one end, were threaded into these holes and held in place by a locking nut on the inner circumference of the ring. The proving rings were calibrated using a Zwick Universal Testing Machine 1478 (Zwick Testing Machines Ltd., Leominster, U.K.). The applied load was read from the Zwick machine, and displacement was measured using a pair of l.v.d.t.s; the instrument configuration is shown in figure 34. Each test was repeated 10 times and the mean value used; care was taken not to exceed the elastic limit of the ring material in any test.

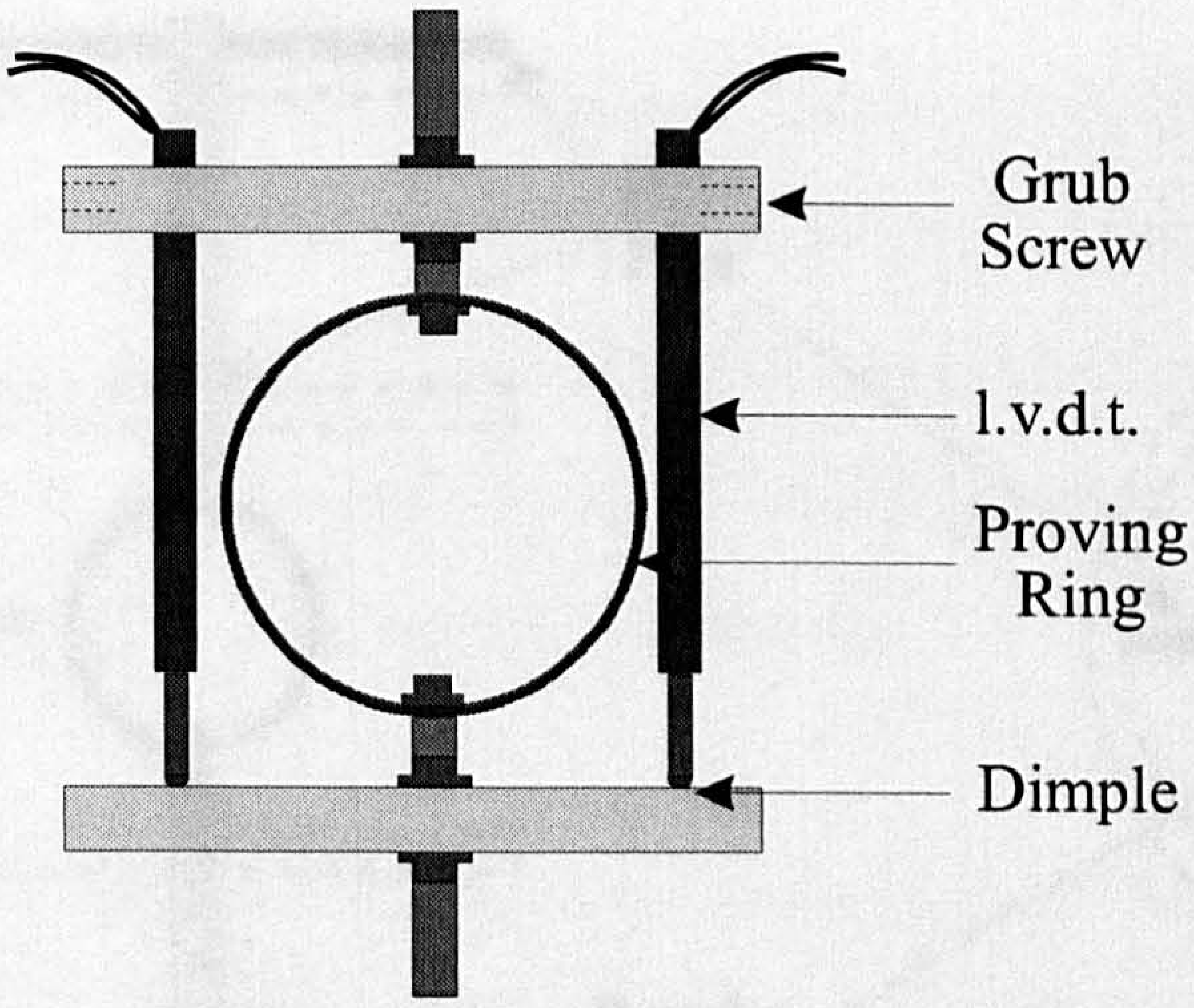


Figure 34 Instrument configuration for proving ring calibration.

The test frame consisted of 4 steel Ilizarov rings, of 200 mm diameter, connected with four connecting rods of 6 mm diameter. The proving ring was connected between the square ends of a pair of 8-hole ranchos. A rancho is an Ilizarov component used for holding pin, and wire, clamps and for the general connection of other components. It consists of a hollow, steel, rectangular block of square cross-section and is relatively stiff in comparison to the other frame components. Two opposite sides of the square cross-section have tapped 6 mm diameter holes in them, the other two sides have plain 8 mm holes; the square ends of the rancho also contain central tapped 6 mm holes.

The 8-hole rancho-proving ring assembly was supported in the frame by 4 pairs of half pins, one pair per ring; in each pair the pins were diametrically opposed. The two pairs in each half of the frame, *i.e.* the sections of the frame distal and proximal to the proving ring, were mutually perpendicular. The frame was symmetrical about a horizontal plane, perpendicular to its major axis, which bisected the proving ring, figure 35. This configuration ensured that the proving ring would be subjected to an axial load, rather than a torsional load, see section 3.2.3.

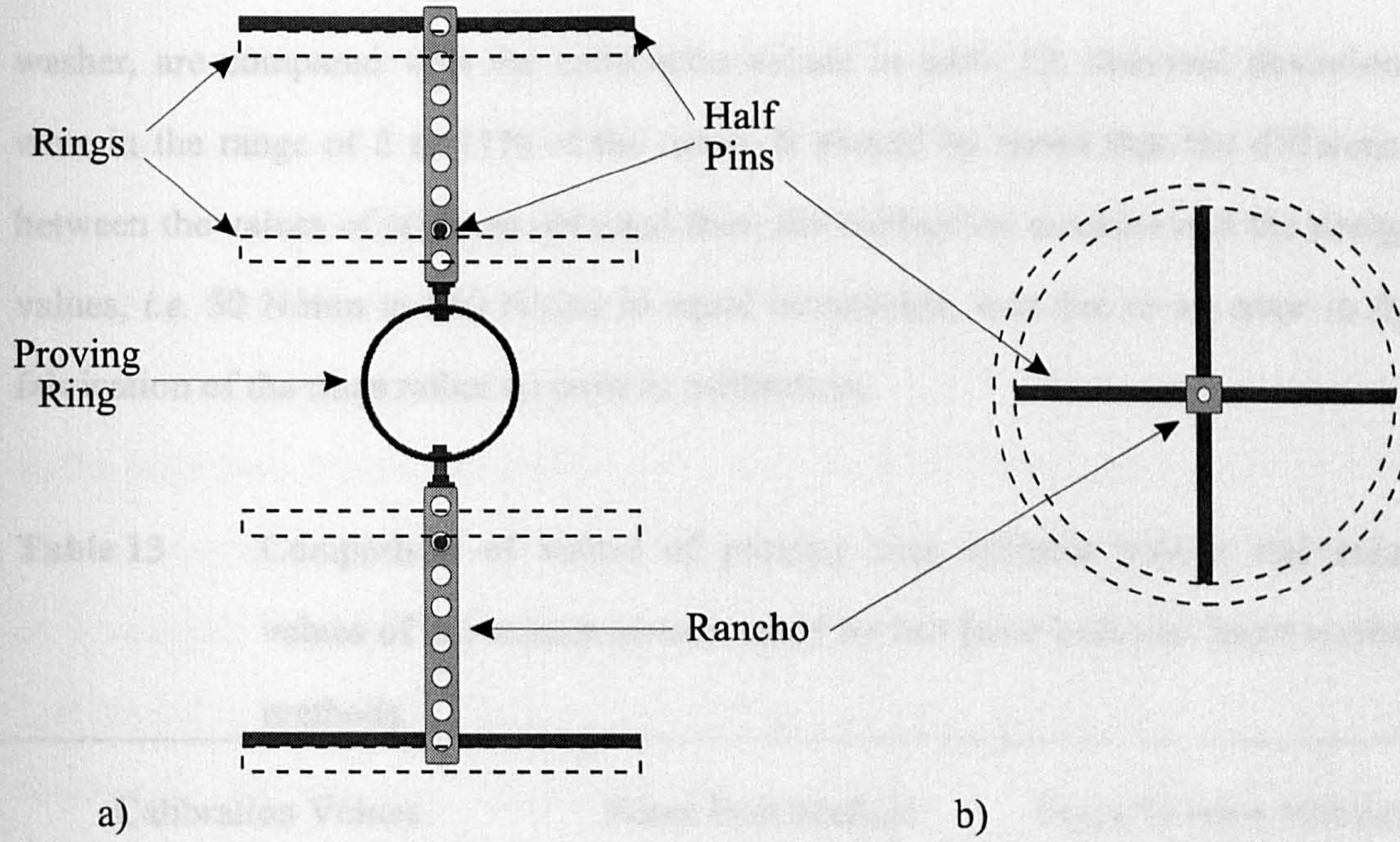


Figure 35 Test rig for the absolute stiffness measuring technique: a) side elevation and, b) plan. Connecting rods and pin clamps have been omitted from the drawing for clarity.

The behaviour of the test rig was only partially analogous to an *in-vivo* fracture-frame system because the presence of soft tissues was not simulated; this had one important effect. When no proving ring was present in the fracture gap, displacement of a ring in one half of the frame produced deformation mainly in that half of the frame. When a proving ring was present in the fracture gap, displacement of a ring in one half of the frame produced deformation in both halves of the frame. By contrast, the presence of soft tissues around the fracture, *in-vivo*, would tend to make the frame deform in the same manner regardless of whether material was present in the fracture gap or not.

Therefore, it was not possible to conduct a meaningful zero reading and so the absolute stiffnesses of the rings could not be determined. Instead, the stiffnesses of the six stiffer proving rings were compared with the stiffness of the least stiff proving ring. Mean values from ten tests with each method, *i.e.* force bolt and force washer, are compared with the calibration values in table 13; standard deviations were in the range of 5 to 11% of the mean. It should by noted that the difference between the values of stiffness obtained from the calibration exercise and the design values, *i.e.* 50 N/mm to 350 N/mm in equal increments, was due to an error in the fabrication of the rings rather an error in calibration.

Table 13 Comparison of values of proving ring stiffness values and mean values of ten measurements made by the force bolt and force washer methods.

	Calibration Values		Force Bolt Method		Force Washer Method	
No.	Stiffness, k_x (N/mm)	Relative change, *i.e.* $k_x - k_1$* (N/mm)	Relative change, *i.e.* $k_x - k_1$ (N/mm)	Difference (%)	Relative change, *i.e.* $k_x - k_1$ (N/mm)	Difference (%)
1	73	-	-	-	-	-
2	115	42	40	-4.2	42	5.7
3	185	112	118	5.3	106	-5.6
4	212	139	144	3.9	129	-7.3
5	262	189	201	6.1	199	5.4
6	331	258	249	-3.3	234	-7.8
7	374	301	323	7.4	320	6.3

* Where k_1 is the stiffness of proving ring number 1.

4.4 Relative Stiffness Measurement

Relative stiffness measurement is based on the principle, explained in the introduction to this section, that the healing fracture, or consolidating section of regenerate, can be considered as a structural member of variable stiffness in parallel with the external frame. Hence, the deformation of the frame in response to a particular load applied to the fracture-frame system is a function of the stiffness of the fracture at that time.

In the hybrid Ilizarov frame, deformation will occur in four main types of components; the wires, rings, pins and, connecting rods. As the technique requires sequential measurements of deformation to be made as healing progresses, measuring wire deflection is impractical because plastic deformation occurs in the wires, leading to a loss of wire tension, see section 3.1. The deflections which occur in the rings tend to be small because they are stiffer than the other components, and for various practical reasons would be difficult to measure. Therefore, it was decided to investigate methods of measuring pin deflection and connecting rod strain. Instrumenting individual frames with strain gauges would be expensive and ineffectual because the gauges would be liable to be damaged between measurements. Therefore, removable transducers were developed; these will be described in section 4.4.2. As mentioned in the introduction to this section, few studies have, to date, investigated the use of relative stiffness measurements under conditions of Ilizarov fixation. One of the main previous studies will be briefly considered below.

4.4.1 The "Maggiore della Carità" Extensometer

An extensometer for conducting sequential relative stiffness measurements on fractures managed with Ilizarov fixation was designed by Ceffa and Bombelli at the Maggiore della Carità Hospital (Novara, Italy) **(104)**, and manufactured by Medicalplastic S.r.l. (Milan, Italy). The extensometer was used in a multi-centre trial involving hospitals in Novara, Mestre, Genova, Padova, and Lecco. Subsequently, 2 prototypes of the device were made available to Smith and Nephew Richards Inc. (Memphis, Tennesee, United States of America) for evaluation. One of the extensometers was given to the present author to evaluate; the main findings of the present author's report will be briefly summarised below.

The device consisted of a plain surgical steel rod 260 mm long with a diameter of 8 mm. For most of its length the rod was of circular section but a 40 mm length beginning at a distance of 40 mm from one end had been ground into a rectangular section approximately 6 mm by 8 mm. On one of the larger two faces of this section four strain gauges have been bonded; two with their long axes in the direction of the major axis of the rod and two perpendicular to it, figure 36. The strain-gauged section of the rod was enclosed in a protective alloy casing. The four strain gauges formed two branches of a Wheatstone bridge, two gauges being used per branch, one vertical and one horizontal, to compensate for temperature effects, etc. Rough balancing of the bridge was provided by an in-line potentiometer. Hence, the instrumentation was capable of measuring the distortion of the strain-gauged face in response to loads applied to the rod as a whole. Data recording was via an XT analogue to digital converter PC card; the tests were controlled by custom software which recorded 300 samples at 100 Hz.

The extensometer was attached to the rings most proximal and distal to the fracture using a pair of clamps. It was necessary to attach the device in the same location for each series of tests and to ensure that the aspect of the strain-gauged face was the same on each occasion; the objective being to ensure that each series of tests was conducted under identical conditions. The test protocol provided for three modes of loading the fracture-frame system: flexion-extension, bending, and walking. The relevant test was selected and the device calibrated. Calibration was performed with the patient lying in repose for the first two tests and standing, with his leg elevated, for the latter. The flexion-extension tests involved the patient flexing and extending the adjacent distal articulation, e.g. in the case of a tibial fracture, the ankle. In the bending tests the patient was asked to elevate the leg about 35 cm and then return it to its initial position before the test time had elapsed; in the walking test the patient was asked to walk as normally as possible. At the end of each test the software reported the maximum, minimum, and mean values in arbitrary units in a range of 1000 to -1000; a graph of the 300 samples was also drawn.

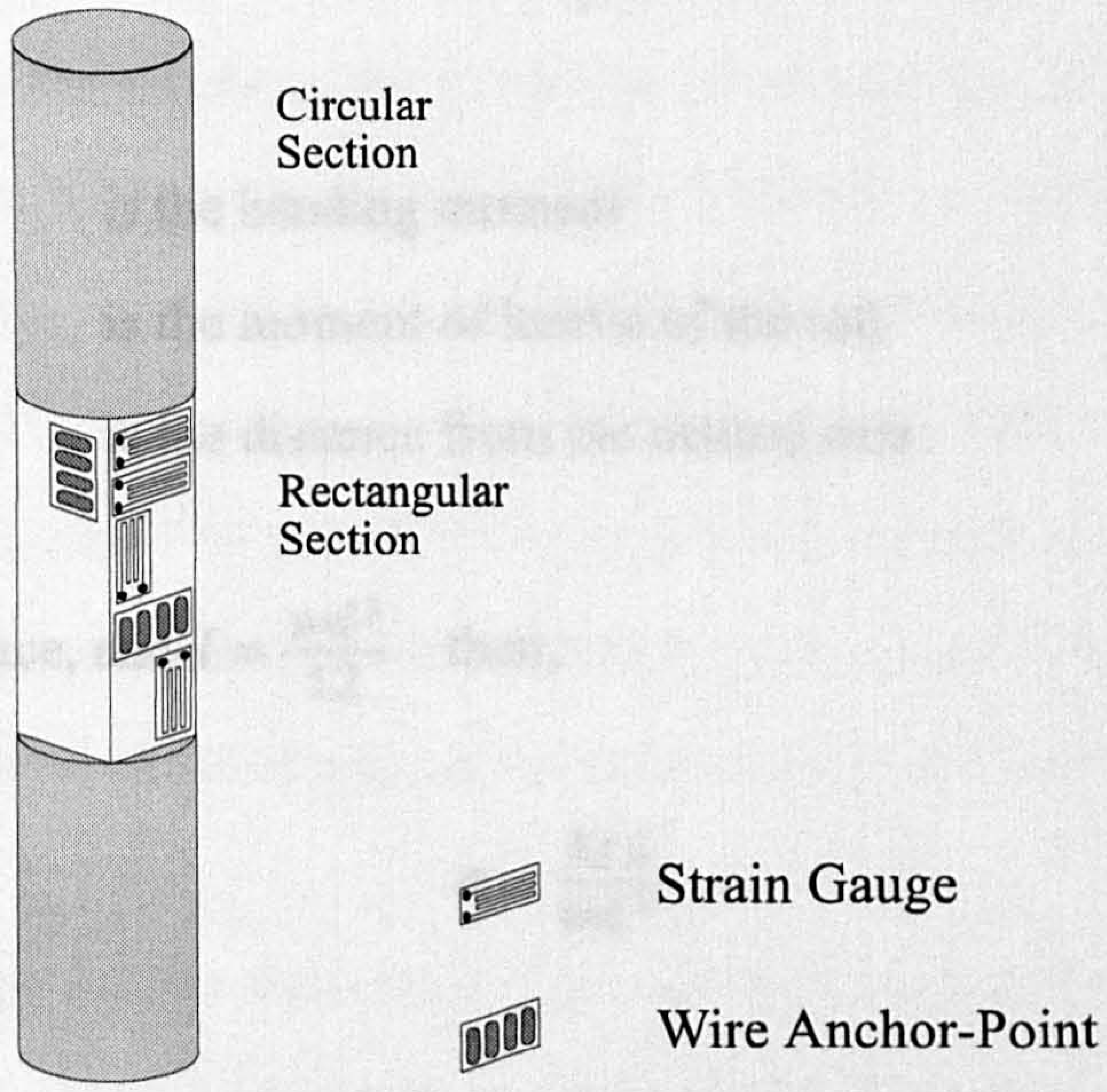


Figure 36 Detail of the strain-gauged section of the "Maggiore della Carità" extensometer.

The most serious deficiency of the device was that it was incapable of distinguishing between bending and axial loads applied to the rod. This was important because in all three tests, *i.e.* flexion - extension, bending and walking tests, both modes of loading were likely to be present and their relative magnitudes might vary as healing progresses, or arbitrarily between each series of tests. If the distortion of the face due to a bending load was equal and opposite to the distortion due to the axial load the net effect would, of course, be that the device measured zero distortion. This would then indicate that the fracture was far stiffer than it in fact was, with possibly disastrous consequences for the patient concerned. Even a modest bending load could have a significant on the output value, as can be shown:

The stress due to a bending load, σ, in a rod of depth d and width w is given by:

$$\sigma = \frac{yM}{I} \qquad (1)$$

where, M is the bending moment

I is the moment of inertia of the rod

y is the distance from the neutral axis

as y = d/2 at the face, and $I = \frac{wd^3}{12}$ then,

$$\sigma = \frac{M6}{wd^2} \qquad (2)$$

The stress due to an axial load, σ', of magnitude F is given by:

$$\sigma' = \frac{F}{wd} \qquad (3)$$

In the case where the strain induced in the face by an axial load is equal and opposite to that induced by a bending load:

$$\frac{F}{wd} + \frac{M6}{wd^2} = 0 \qquad (4)$$

i.e.

$$F = \frac{-6}{d} M \qquad (5)$$

As d is small compared to, for instance, the diameter of the rings it can be readily seen from equation (5) that even a modest bending load will achieve the same strain as a large axial load. It should also be noted that the effect will be more significant in modified and hybrid frames, because, being stiffer, the pins present in such frames will transmit a bending load more efficiently to the rings, and hence to the rods, than wires would.

In addition to the limitations of the extensometer, the system as a whole had some serious limitations. No provision was made for filtering the signal and as a result the signal was very noisy. Neither the sampling rate nor the number of samples recorded could be altered by the operator and so the duration of each test was fixed at 3 seconds. Whilst it would be possible for the majority of patients to accomplish the bending and flexion-extension tests in this period, many would have difficulty completing the stance phase of gait, on the affected limb, within the available time.

However, the most serious flaw of the test protocol was the assumption that it was possible to conduct each series of tests under identical conditions, *i.e.* that the only variable was the stiffness of the healing fracture. Attaching the device to the same location on the frame and ensuring that the aspect of the strain-gauged face is the same for each series of tests is easily accomplished. Ensuring the same range of limb excursion in the bending and flexion-extension tests is less trivial and ensuring that the patient adopts an identical gait pattern in the walking tests is, when it is considered that it may be necessary to conduct biweekly tests over a period of 12 months or more, impossible. Hence, the magnitude of the loads applied to the frame would be likely to vary arbitrarily between each series of tests. As it was not possible to measure the loads, this would preclude any meaningful conclusions being drawn from the data.

Given the discussion above, it is not surprising that, of the 103 patients included in the Italian trials, the system failed to indicate the progression of healing in 84 cases (**105**). However, in concept, the system had several advantages, including that it was relatively cheap. The device could be quickly, and easily, attached to the frame, and the tests rapidly accomplished; an important advantage in a clinical environment.

4.4.2 Instrumentation

Two main conclusions can be drawn from the present author's study of the Maggiore della Carità extensometer. Firstly, in any system of relative stiffness measurement, the manner in which the fracture-frame system is loaded should be as simple as possible, *i.e.* a pure axial or bending load should be applied. It should also be possible to quantify the magnitude of the applied load easily. Secondly, any transducer which may subjected to a mixed load because of the manner in which the fracture-frame system deforms, should be able to distinguish between the components of the mixed load.

Therefore, the starting point for the design of any system of relative stiffness measurement should be the choice of the mode in which the fracture-frame system is to be loaded; the transducers, other components, and protocol, should then be designed around this central premise. In the case of the present study, a static, axial load was chosen; there were two reasons for this choice. Firstly, a static, axial load is easy to apply, it merely involves the patient weight bearing. Secondly, the magnitude of the load can be easily quantified at the time that measurements are taken by placing a load cell under the patients foot. Two transducers were developed as part of this study; one to monitor pin deflection and the other to monitor connecting rod strain.

Pin deflection transducer

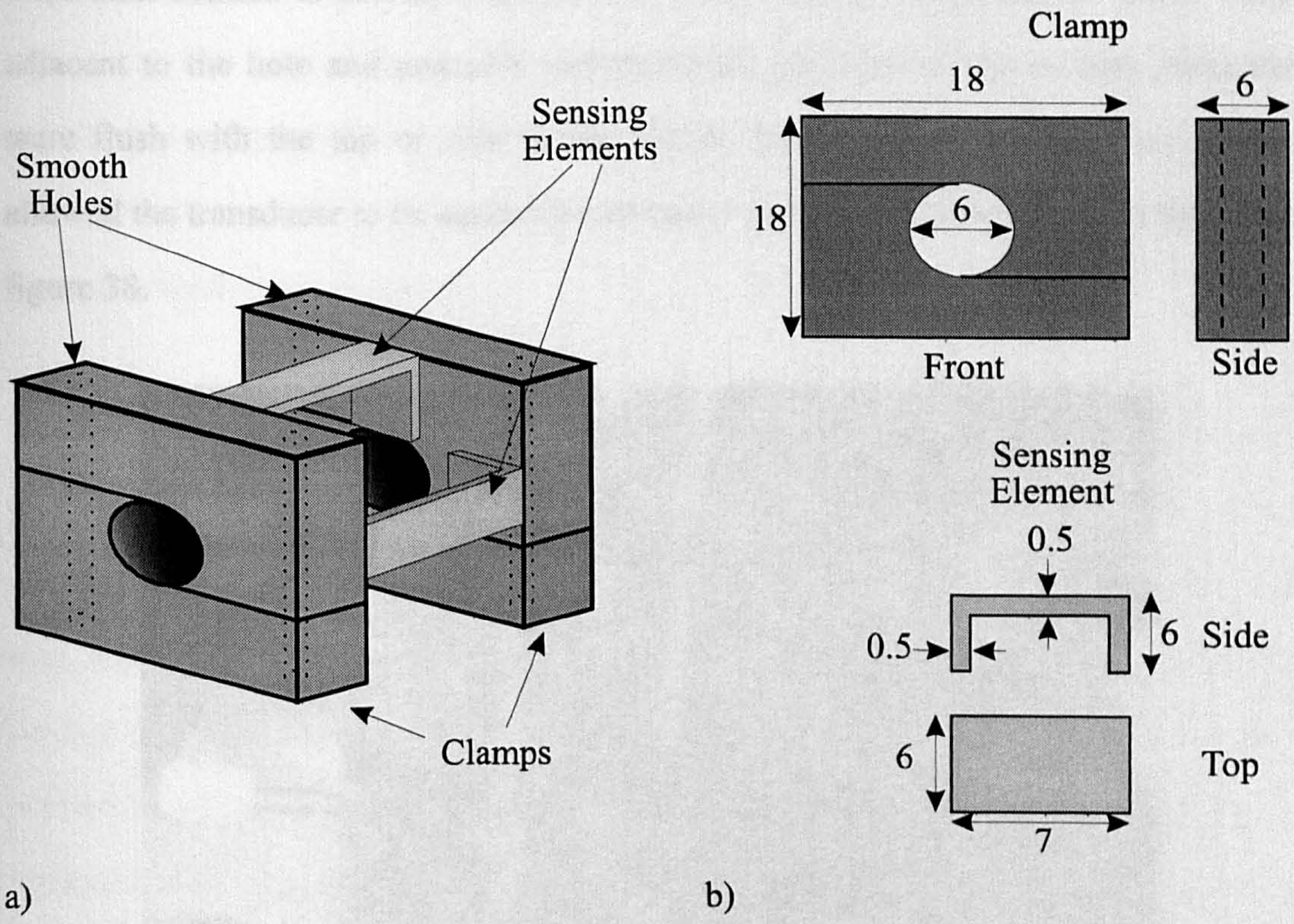


Figure 37 The pin deflection transducer, a) and, dimensions of the clamps and sensing elements, b). Not to scale.

The pin deflection transducer consisted of 2 clamps connected together by 2 sensing elements, the exterior surface of each of which had a strain gauge bonded to it, figure 37. Each clamp was fabricated from a single block of brass 18 mm square and 6 mm thick. A hole of 6 mm diameter was drilled through the centre of the major aspect of the block; a further two holes of 3 mm diameter were drilled through one of the minor aspects of the block, perpendicular to the first hole. The latter two holes were centred on the major axis of the minor aspect, 3 mm from each end. Two cuts were then made through the block, perpendicular to the 2 mm holes and the major aspect of the block, intersecting with the 6 mm hole at diametrically opposed points; *i.e.* the block was cut into two pieces. Each of the sensing elements was ground from a single block of brass to the dimensions shown in figure 37. The sensing elements were then bonded to corresponding halves of the clamps in positions which were adjacent to the hole and mutually perpendicular; the tops of the sensing elements were flush with the top or side of the clamp. Bolts inserted in the 3 mm holes allowed the transducer to be assembled around 6 mm diameter half pins, as shown in figure 38.

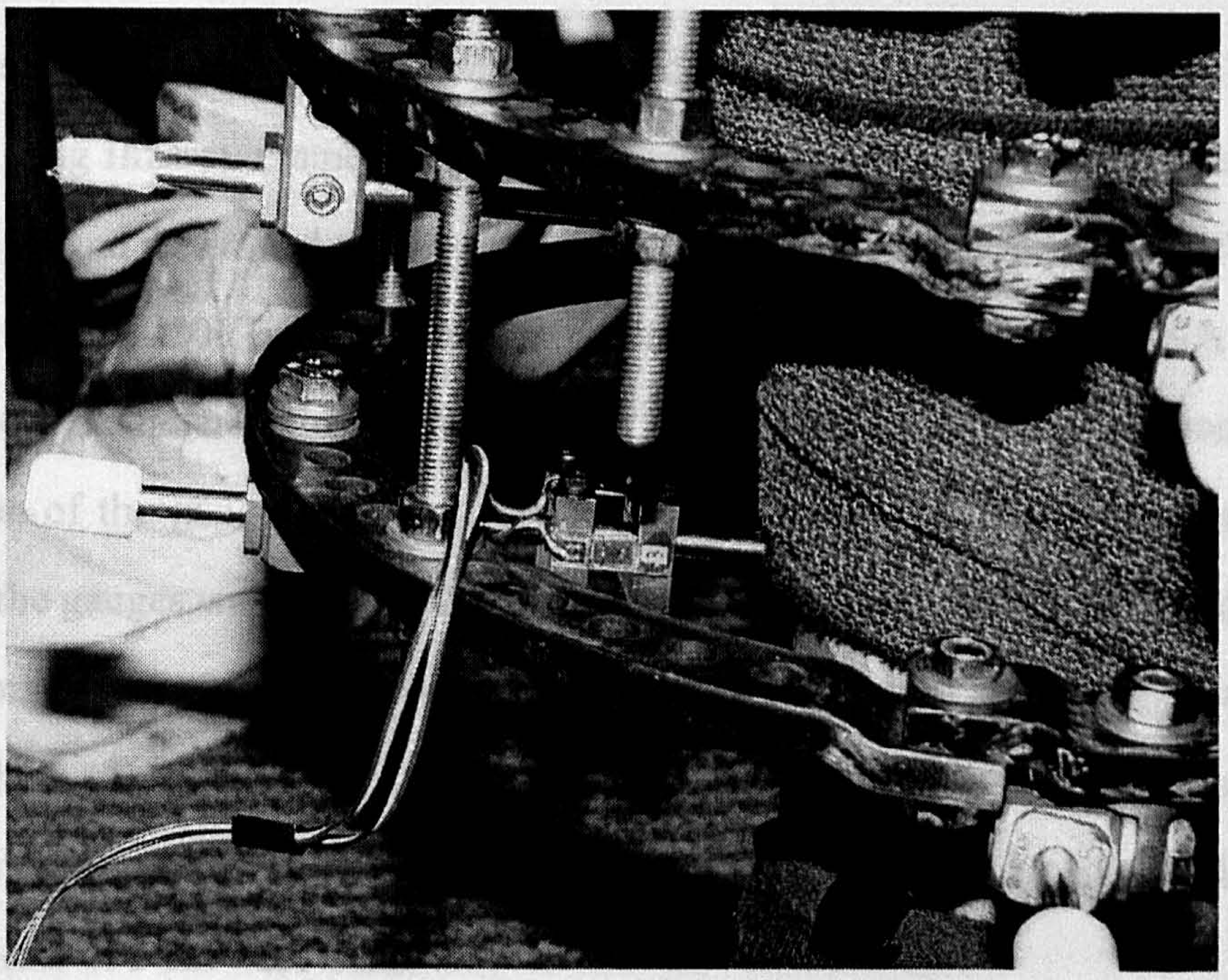


Figure 38 The pin deflection transducer *in-situ* on a hybrid Ilizarov frame.

A single EA-06-062AQ-350 self-temperature compensating strain gauge was bonded to the exterior face of each of the sensing elements using M Bond 610 adhesive cured at 150 °C; the installation was then protected using M Coat C. The gauges, adhesive, and protective coating were supplied by Measurements Group UK Ltd. (Basingstoke, UK). Each of the strain gauges was wired into a three-wire circuit, *i.e.* a half bridge in which one of the arms is provided by the strain gauge and the other by a completion resistor. The excitation voltages and signal conditioning were provided using a DMC Plus digital amplifier controlled by Catman 32 data acquisition software, both supplied by Hottinger Baldwin Messtechnik (UK) Ltd.

(Harrow, UK). The Catman 32 software was mounted on a Carrera Pentium II Explorer notebook PC, Carrera Technologies Ltd. (London, UK). An excitation voltage of 5 V and measuring rate of 75 Hz were used; signal conditioning was provided via a Bessel filter at 7.5 Hz.

Instrumented connecting rod

The transducer for monitoring connecting rod strain was fabricated from a standard 260 mm long Ilizarov connecting rod, of 6 mm diameter. The central 40 mm of the rod was ground down and polished so that it had a square cross-section, of side 4.2 mm. An EA-03-030YB-120 delta strain gauge rosette was bonded to each of faces centred on the intersection of the major and minor axes. Supply, bonding and protection of the gauges was as described above for the pin deflection transducer. Each of the gauges was wired in a separate three-wire circuit, giving a total of twelve connectors. In practice, only two of the rosettes were used in any test, the other pair provided a back-up should one of the devices fail. The excitation voltages and signal conditioning were provided as above, except that a measuring rate of 20 Hz and a filtering rate of 5 Hz were used.

The use of a standard Ilizarov connecting rod meant that the transducer could be used to temporarily replace one of a frame's connecting rods for the duration of the test. In practice however, it was found to be more convenient to attach the transducer to the exterior of the frame using a pair of 3-hole ranchos and half pin clamps, figure 39.

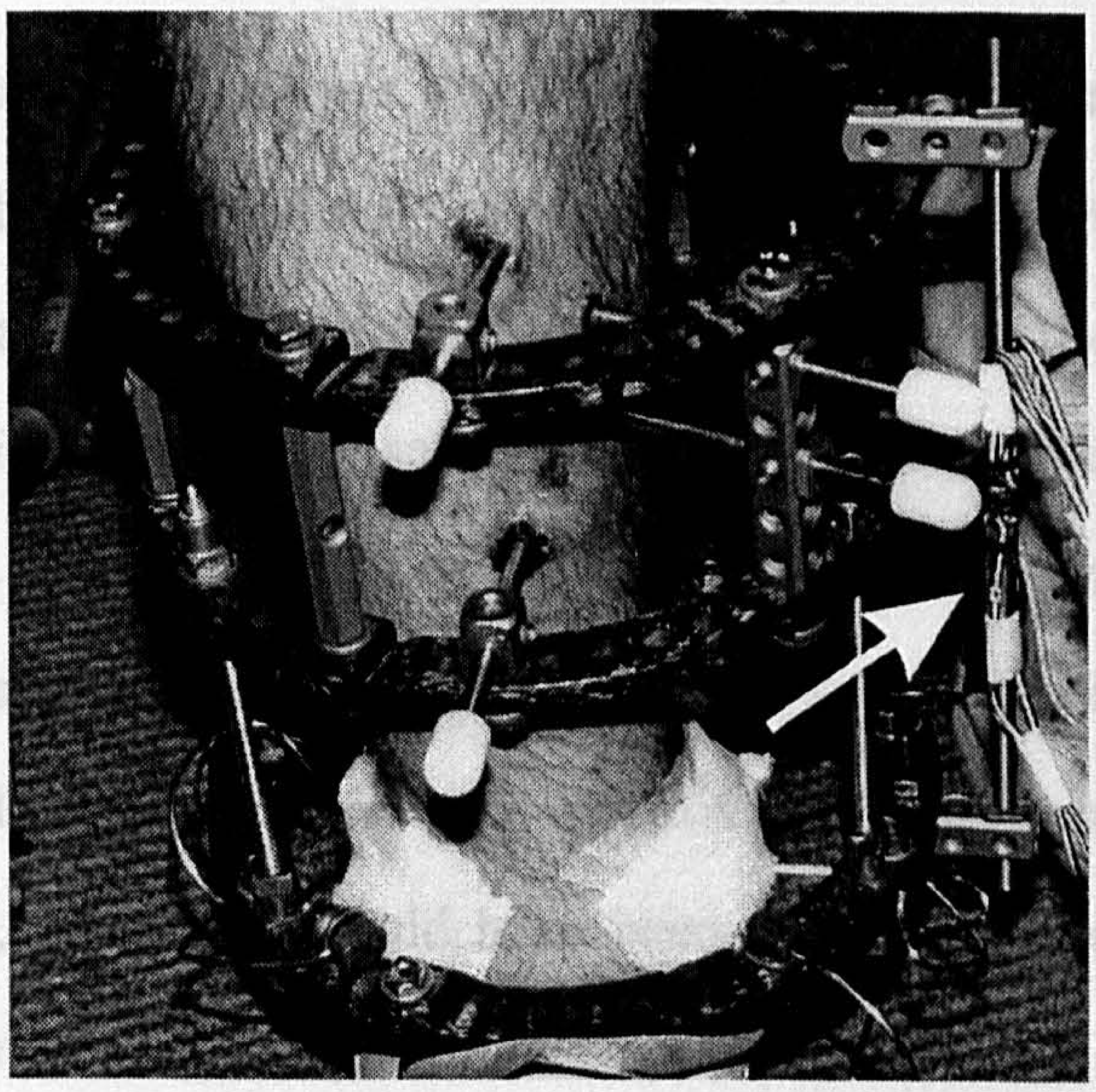


Figure 39 The instrumented connecting rod, indicated by an arrow, attached to a hybrid Ilizarov frame by means of a pair of 3-hole ranchos and pin clamps.

4.4.3 *In-vitro* Tests

Pin deflection transducer

The test rig for the pin deflection transducer was extremely simple. Two 5-hole ranchos were connected together with a short connecting rod, and locking nuts, to form a symmetrical 'T' shaped assembly. A pin clamp and a standard Ilizarov titanium half pin, of 6 mm diameter, were then inserted into one of the short arms of the rancho assembly. The assembly was then locked in a vice with the half pin horizontal and the shaft of the 'T' assembly vertical; a spindle, on which masses could be hung, was then suspended from the unclamped end of the half pin. The objective of using the 'T' shaped rancho assembly to hold the pin, instead of a single rancho, was to minimise swivelling of the pin in the jaws of the vice. The transducer was then attached to the half pin and a series of masses was placed on the spindle; readings were taken after each increment.

The test was repeated several times, the objective being to assess the effect on the transducer output of a) orientation of the sensing elements with respect to the neutral axis of the half pin and b), the magnitude of torque applied to the clamp bolts. Small variations in the orientation of the sensing elements with respect to the neutral axis of the half pin, *i.e.* small rotations of the transducer about the neutral axis, were found to have a relatively insignificant effect on transducer output; this was an important result. Had output been very sensitive to minor variations in sensing element orientation, a protocol would have been required to ensure that transducer orientation was the same for each clinical test. However, the results of the tests showed that the operator judging by eye that one element was "horizontal" and one "vertical" would be sufficient. The effect of transducer location along the major axis of the pin was not considered because there is generally little space between the pin clamp and the limb; in practice, a slip gauge could be used to ensure a constant transducer to clamp separation. Not surprisingly, the magnitude of the torque applied to the clamp bolts had a significant effect on transducer output.

Instrumented connecting rod

An axial load was applied to the rod in order to assess the repeatability of strain measurements made with the rod. A universal coupling was attached to each end of the rod. One of the couplings was then attached to a 'T' shaped rancho assembly, constructed as described above, which was subsequently locked in the jaws of a vice. A spindle was attached to the other universal coupling; a series of masses was then placed on the spindle and readings taken after each increment. The test was repeated ten times; the rig was disassembled and reassembled after each test. Standard formulae were then used to resolve the rosette gauge outputs into strain components (**113**). The results of the test are shown in figure 40, and table 14. The rod was also tested under a combined axial and bending load. This was achieved by removing the upper universal coupling and connecting the rod directly to the 'T' shaped rancho assembly locked in the jaws of the vice. The spindle was then loaded as described above and before each measurement a small load was applied at the base of the rod, perpendicular to its major axis, using a spring balance.

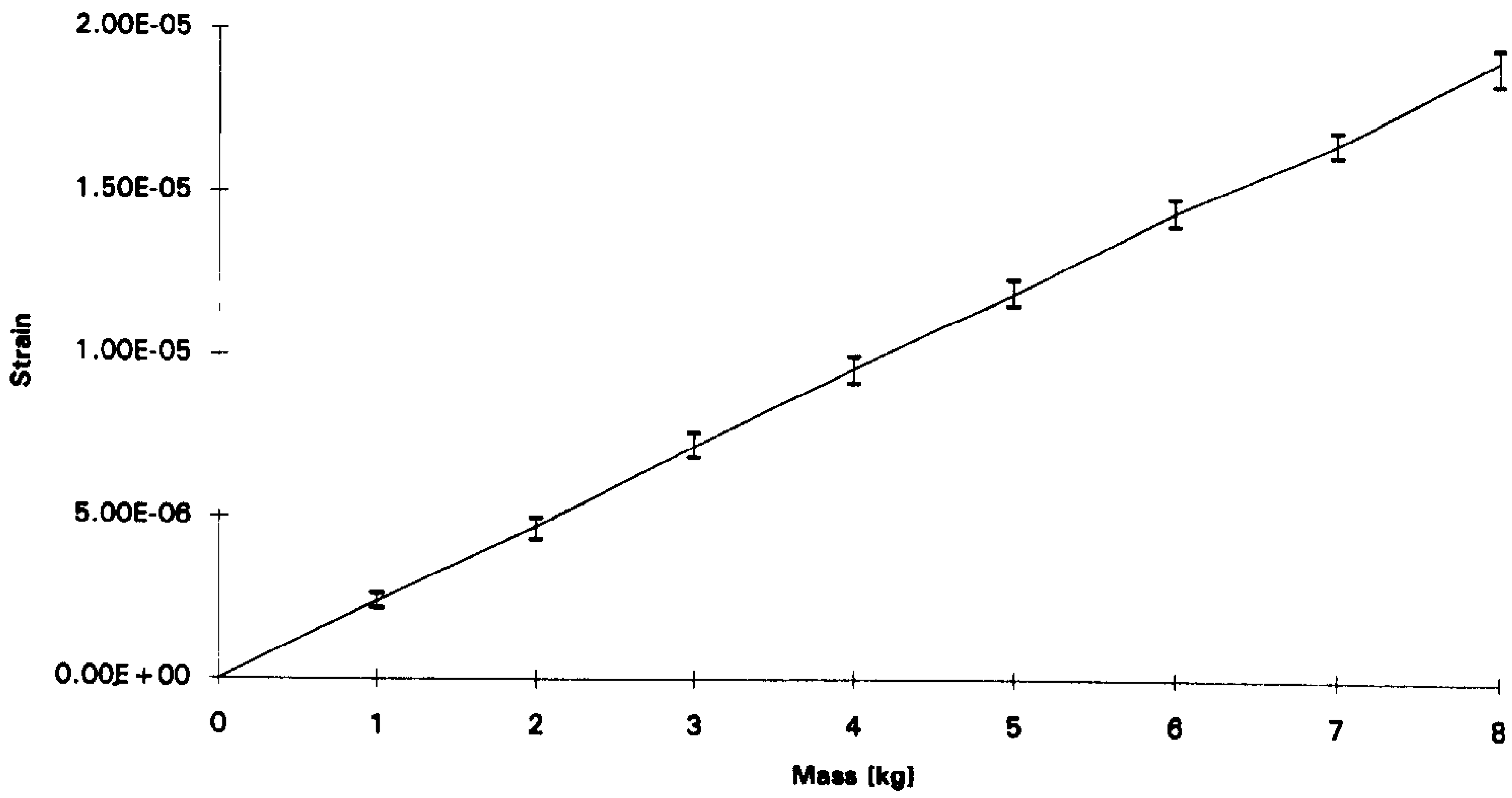


Figure 40 Mean strain measured by the instrumented connecting rod versus spindle mass; the graph shows the mean value and range over ten tests.

Table 14 A comparison of theoretical strain and mean strain, over ten tests, measured with the instrumented connecting rod.

Spindle Mass [kg]	Theoretical Strain	Mean Strain	Error [%]
0	0.00E+00	0.00E+00	-
1	2.38E-06	2.40E-06	0.89
2	4.76E-06	4.69E-06	-1.45
3	7.14E-06	7.19E-06	0.71
4	9.52E-06	9.60E-06	0.83
5	1.19E-05	1.18E-05	-0.42
6	1.43E-05	1.44E-05	0.73
7	1.67E-05	1.65E-05	-0.96
8	1.90E-05	1.91E-05	0.48

4.5 Discussion

Reference to table 13 shows that neither method of determining the absolute tensile stiffness was particularly accurate; both methods had a low repeatability. However, these factors should be considered in context. The technique was proposed as an alternative to the conventional techniques of physical manipulation and plain radiography. Physical manipulation, where possible, has been shown to be unreliable in 83 % of cases (51), plain radiography has been shown to be unreliable in 50 % of cases (54). In practice, a more serious deficiency of the technique is that it would require 3 or 4 sets of instrumentation, each consisting of 3 components, to be attached to the frame. Therefore, in many cases it would be necessary to partially dismantle the frame in order to accommodate the instruments; this, together with the need to take multiple measurements, might mean that the procedure took up to a couple of hours. However, the technique was not conceived for the routine monitoring of fracture healing but as a research tool, and for one-off determinations in difficult cases. Additionally, it could be argued, that many routine radiographical procedures, such as arthrographs, take a similar length of time to perform.

It was originally conceived, by the present author and the consultant surgeon acting as co-researcher on the project, that the procedure would be conducted on conscious patients. Patients undergoing distraction osteogenesis routinely apply distraction in increments of up to 0.75 mm, apparently without discomfort. However, prior to the commencement of the clinical trials it was decided that the procedure could only be conducted under general anaesthesia; one of the clinical staff felt that the procedure would be uncomfortable for the patients otherwise. Unfortunately, no allowance had been made in the project budget to compensate the United Bristol Healthcare Trust for theatre time and, given the probable duration of the procedure, it was not practical to perform it during operations to apply and remove frames. Therefore, it was not possible to conduct *in-vivo* trials of the technique.

The pin deflection transducer was also dropped from the *in-vivo* trials; there were two main reasons. Firstly, at the time the transducer was designed and fabricated, surgeons at the Bristol Royal Infirmary were predominantly using half pins of 6 mm diameter, but by the time the *in-vivo* study was due to start they had switched to using a mixture of 4, 5, and 6 mm diameter pins. This reduced the possible number of attachment points for the transducer; not all pins are viable attachment sites anyway because of the required minimum ring to limb separation. The second reason, which has already been mentioned above, is that the transducers output is very sensitive to clamping torque. In bench tests it is relatively easy to ensure that the torque applied to the clamp bolts is equal for each test; *in-vivo* it is far more difficult because of restricted access, see figure 38.

The *in-vitro* trials of the instrumented connecting rod showed that it had a reasonably linear output over the required range of load and reasonable repeatability. The device required only two attachment points and was easy to apply. Additionally, the device could be used on any type of Ilizarov frame, *i.e.* original, modified or hybrid. By analogy with the Maggiore della Carità extensometer, it was assumed that the test protocol could be readily accomplished in a clinical environment. The *in-vivo* trial of the device will be discussed in section 5.

CHAPTER 5. *In-vivo* Study of Relative Stiffness Measurement

In the previous section the design and *in-vitro* testing of an instrumented connecting rod was discussed; in this section an *in-vivo* trial of the device conducted by the present author at the Bristol Royal Infirmary will be discussed. Section 5.1 gives some relevant details of the 10 patients included in the trial; fuller case histories of these patients can be found in appendix I. In section 5.2 the test protocol will be described; the results obtained from the study will be presented and discussed in section 5.3. The implications of the findings of the study are discussed and suggestions for further work given in section 5.4.

5.1 Patients and Ethical Considerations

The Bristol Royal Infirmary, B.R.I., is a national centre for the Ilizarov technique. Patients are referred from the whole of the south west peninsular and south Wales; the boundaries of the territory are Swindon in the east and Birmingham in the north. The majority of the patients who are not resident in Bristol, or its immediate environs, receive physiotherapy in their locality and only attend the B.R.I. for clinics; generally at 4 - 6 week intervals. Patients resident in Bristol area, attend the B.R.I. for physiotherapy once a week, in theory at least. From a review of previous studies, a weekly interval between relative stiffness measurements seemed appropriate, and so subjects for the study were recruited from those attending physiotherapy at the B.R.I. To minimise transport costs, the measurements were made during the patients' normal physiotherapy sessions.

Case histories of the patients included in the study are given Appendix I; some relevant details are summarised in table 15. The patients are coded T1 to T9, and F1; T indicates a tibial fracture and F, a femoral fracture. The severity of the patients injury was assessed on a scale devised by Richardson *et al.* (**52**), shown in table 16.

The degree of frame symmetry about a plane through the fracture perpendicular to the long axis of the bone was also assessed for the hybrid frames. In section 3.2.3, it was shown that magnitude of shearing which can occur at the bone ends in response to an axial load is related to the symmetry of such frames about the fracture gap.

Table 15 *In-vivo* study of relative stiffness measurement: Patient data.

Patient Code	Sex	Age	Injury Severity	Frame Type[a]	Frame Symmetry[b]	Load Applied During Test [N]	Duration of Healing[c] [weeks]
T1	M	28	1 (5)[d]	H	A	295	16
T2	F	23	2	H	S	490	45
T3	M	37	1	O	-	295	10
T4	M	33	3	O	-	295	-[e]
T5	M	48	3	H	S	295	16
T6	M	29	2	H	S	490	-[e]
T7	M	40	1	H	A	295	22
T8	M	49	5	H	S	490	13
T9	M	32	3	H	S	295	20
F1	M	25	2	H	A	295	16

a: H = Hybrid, O = Original
b: A = significantly asymmetric, S = approximately symmetric
c: Weeks elapsed between frame application and the fracture being judged clinically united.
d: Patient T1 was a re-fracture following premature frame removal; the figure in brackets refers to the original injury.
e: The fractures of patients T4 and T6 had not united by the time the study ended on 22nd January, 1999.

Table 16 Injury severity classification. After Richardson *et al.* (52).

Severity Grade	Type of Fracture
1	Not compound, not comminuted.
2	Significantly compound, not comminuted.
3	Not compound, severely comminuted.
4	Compound and comminuted.
5	Bone loss.

Generally, initial measurements were made shortly after the patients began weight bearing; in the majority of cases this was within 4 weeks of frame application. The one exception was patient T2, who had a fracture which exhibited particularly slow healing; measurements on patient T2 were initiated 36 weeks after frame application because sequential radiographs had shown little progress towards union. Patients T2, T4 and T7 had fractures which were trauma residuals, *i.e.* fractures which had failed to unite under a previous regime of management. The fractures of patients T2 and T7 had been managed using intramedullary nailing; the fracture of patient T4 had been managed using an Orthofix uniaxial external fixator. Patient T1 had experienced a re-fracture shortly after the removal of an Ilizarov frame.

With the exception of patients T6 and T4, the fractures of all patients achieved union during the course of the study. The fracture of patient T6, which was effectively an osteotomy because a large segment of bone had been resected, achieved a partial bony bridging of the fracture gap, as has been discussed in section 3.2.3. By 12 weeks after frame application, the fracture of patient T4 had developed into an atrophic non-union. Patient T8 had suffered significant traumatic bone loss and so, following fracture union, distraction osteogenesis was initiated. The frames of all the other patients were removed during the course of the study; none of the patients experienced re-fracture.

Approval for the study was obtained from the Research Ethics Committee, R.E.C., of the United Bristol Healthcare Trust (R.E.C. project code E3385); informed consent was obtained from the patients who participated in the study. All decisions regarding the management of the patients' fractures were made using conventional radiological and clinical methods of assessment. The tests were performed by the present author in the gymnasium of the Physiotherapy department at the Bristol Royal Infirmary, with a physiotherapist in attendance.

5.2 Test Protocol

The procedure involved the following four basic steps:

i) The patient was seated between a pair of parallel bars and the instrumented connecting rod was attached to the exterior of the patients frame.

ii) The patient was then asked to stand with the foot of the normal limb resting on a block and the foot of the injured limb resting on a set of scales. Some of the patients required the parallel bars to maintain stability whilst standing-up, but the patients were discouraged from using the bars for support during the tests.

iii) The patient was then asked to bear all his weight through the normal limb but to maintain contact between the foot of his injured limb and the scales; a zero reading of the instruments was then taken.

iv) The patient was then asked to bear a predetermined amount of his weight through his injured limb and a second reading of the instruments taken.

Steps iii) and iv) were then repeated until 10 pairs of readings had been obtained.

Relative stiffness monitoring techniques involve considering the fracture as a member of variable stiffness in parallel with a frame of constant stiffness. Hence, the magnitude of deformation occurring in the frame in response to a particular load applied to the fracture-frame system is a function of the stiffness of the fracture at that time. Therefore, sequential measurements of an aspect of frame deformation can be used to monitor the progress of fracture healing, provided that all variables, other than the fracture stiffness, are excluded, *i.e.* that each test of the series is performed under identical conditions. In the protocol described above there are three factors which would compromise the validity of the results if not controlled: a) the position of the instrumented rod, b) the magnitude of load applied and, c) the frame configuration. Precautions were taken to ensure that these factors were the same for each test session of the series; these will be briefly discussed below.

Instrument position

At the start of the patients first test session an assessment was made of the most convenient location to attach the rod to the frame; where possible, the rod was attached on the lateral aspect of the frame for the convenience of the patient. The rod was attached to the frame using a pair of ranchos and half pin clamps, see figure 39. Care was taken to ensure that the rod was attached parallel to the long axis of the frame and that no pre-load was applied to the rod during attachment.

The procedure involved attaching the ranchos to rings situated distal and proximal of the fracture. The ranchos were attached, with their long axis perpendicular to a tangent to the ring at the point of attachment, using nuts, bolts and washers; the nuts were not completely tightened at this stage. The rod was then inserted into pin clamps held by the ranchos and moved up and down, in a direction parallel to the long axis of the frame. If the rod did not run smoothly through the pin clamps, the ranchos were rotated slightly until it did. The upper pin clamp was then locked and the nuts holding the ranchos were tightened. The rod was then released again and, again, moved up and down in the direction of the long axis of the frame. If it ran smoothly through the clamps, both pin clamps were then locked; if it did not, the ranchos were released and the whole procedure repeated.

The location of the rod was then photographed using a C1400 digital camera (Olympus Optical Co., London, UK) and the length of section of the rod protruding from the proximal pin clamp measured. On subsequent test sessions the rod was replaced in the same location by reference to the photograph and measurement. The faces of the central region of the rod, which had square cross-section, were labelled A to D; the rod was always attached with face A outermost.

Magnitude of applied load

The magnitude of the load applied by the patients during the tests was measured using a set of scales (Salter Weigh Tronix, London, UK). The scales were calibrated prior to each test session using the same pair of training weights with a nominal mass of 20 kg. At the first test session, patient was asked to assess the maximum load he could bear on his injured limb without undue discomfort. The patient was then asked to assess the maximum load he could apply repeatedly and accurately, *i.e.* without the scale reading dithering. The objective of asking the patient to assess the maximum load twice in this manner was to encourage him to choose a realistic, easily achievable, test load. In most of the patients the test load corresponded to a scale reading of 30 kg, in three it was 50 kg; table 15 gives the equivalent loads.

During tests a block was placed under the foot of the patient's normal limb so that both feet were approximately level. Zero readings were taken with the foot of the patient's injured limb just touching the surface of the scales and the scale reading at 0 kg. The patient was then asked to slowly shift weight to the injured limb until the scale reading read the appropriate amount. Loaded readings were taken with the patient standing with a straight back and adopting a stance as close to normal as possible. If the scale reading dithered during a measurement, the readings were discarded and the measurement repeated.

Frame configuration

Prior to the start of the *in-vivo* study it had been assumed that changes to the frame configuration, due either to deliberate alterations made by the surgeons or the failure of frame components, would be the most likely cause of the invalidation a series of tests; this assumption was one of the main motivations for the study described in section 3.2. During the first test session the frame was photographed. At subsequent sessions the patient was asked whether any alterations had been made to the frame, and the frame was checked against photographs whilst the instrumented rod was attached.

In practice, no significant alterations were made to the configuration of the frames of the patients included in the study, prior to fracture union. Once the fractures had been judged clinically united, the frames of all patients except T8, who was to undergo distraction osteogenesis, were de-stabilised by the removal of some of the connecting rods. However, measurements were stopped once the fracture was clinically united and so this had no effect on the study. De-tensioning of the fine wires due to plastic deformation was observed in most of the frames, but the wires were re-tensioned by the clinical staff prior to test sessions.

5.3 Results and Discussion

Before reviewing the results of the clinical trial, the results which might have been expected will briefly discussed. Relative stiffness monitoring techniques are based on the assumption that a simple load sharing relationship exists between the fracture and the external frame. As the stiffness of the healing fracture increases, its capacity to carry load increases. Hence, as healing progresses, the proportion of load carried by the frame decreases and that carried by the fracture increases. Therefore, the magnitude of an aspect of frame deformation, such as connecting rod strain, in response to a particular load applied to the fracture-frame system, will decrease as healing progresses. This can be illustrated by reference to a previous study by Kristiansen and Borgwardt (57).

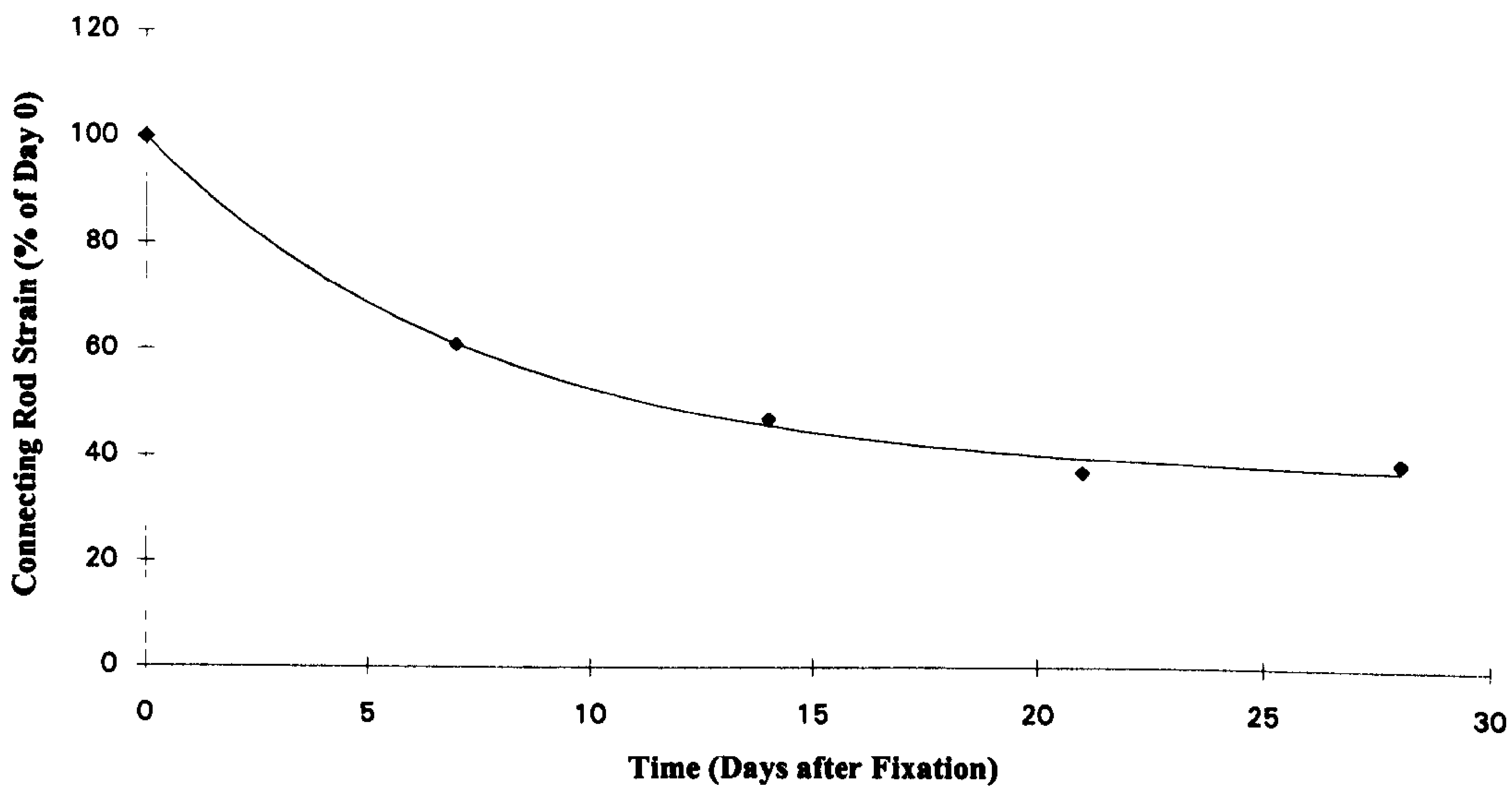
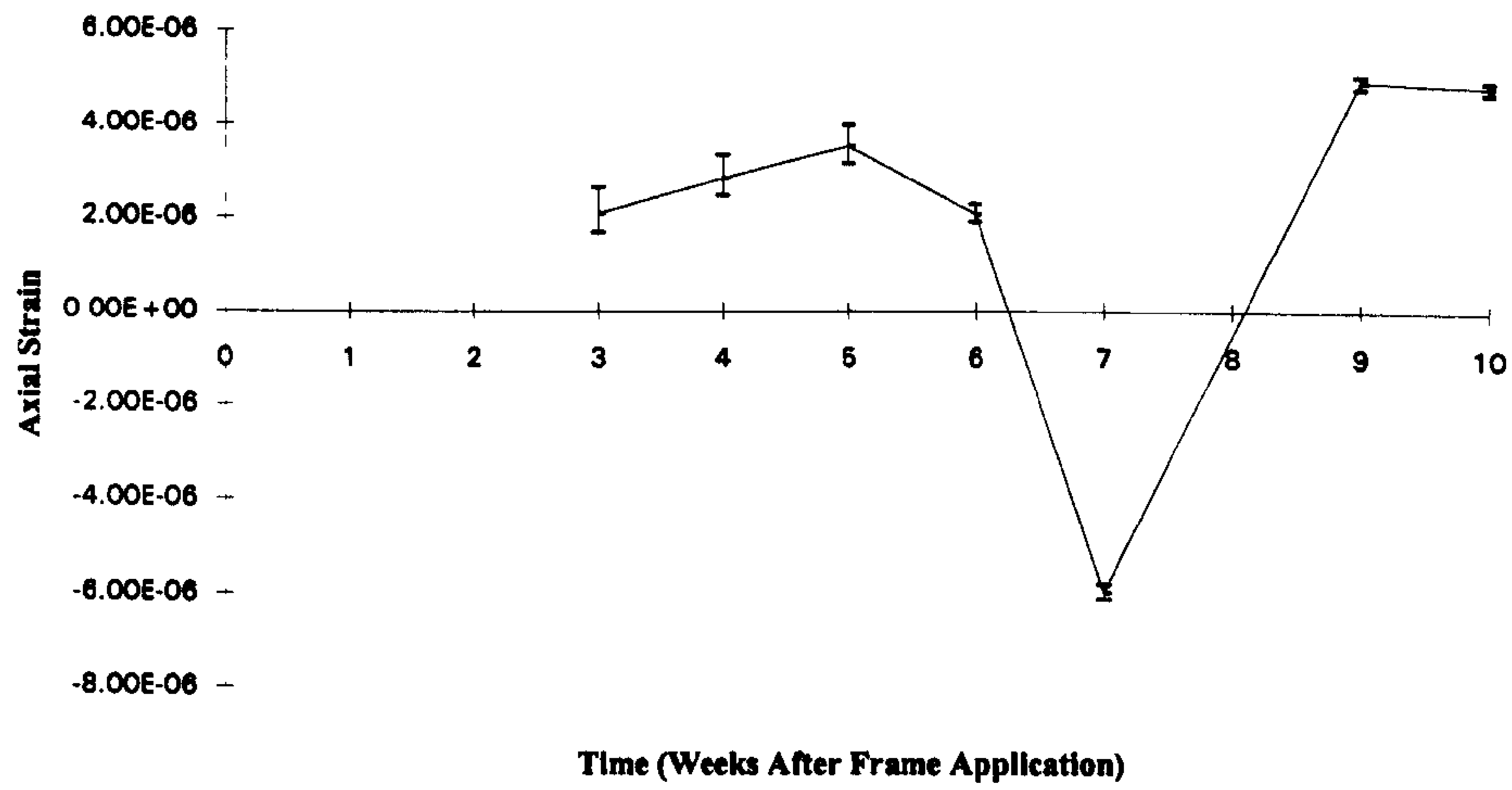


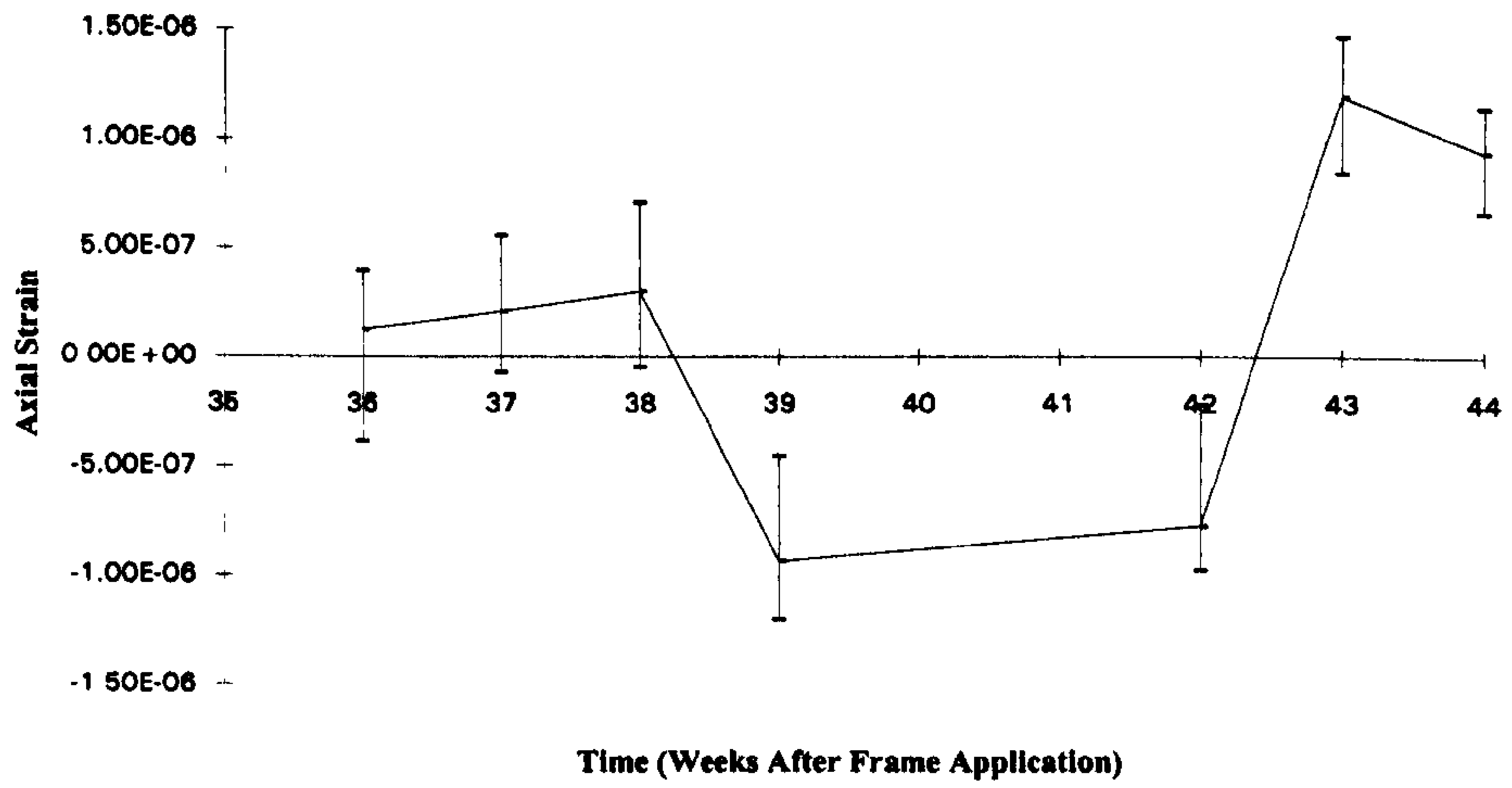
Figure 41 Connecting rod strain versus time for a patient with a fracture of the neck of the humerus managed with a uniaxial fixator. Data from Kristiansen and Borgwardt (57). A curve of the form $y = a + be^{-kx}$ has been fitted to the data by the present author.

Kristiansen and Borgwardt monitored connecting rod strain in 7 patients with fractures of the neck of the humerus. The fractures were managed using uniaxial fixators which had a strain gauge bonded to the surface of the connecting rod. Loading of the fixator was achieved by horizontal extension of the patient's arm; the bending strain induced in the connecting rod by the effects of gravity was then measured. Measurements were made immediately after fixation and then at weekly intervals; on each occasion ten measurements were made. Results from one patient are shown in figure 41; it would appear that the assumption that a simple load sharing relationship existed between the fracture and the frame, was valid in this case.

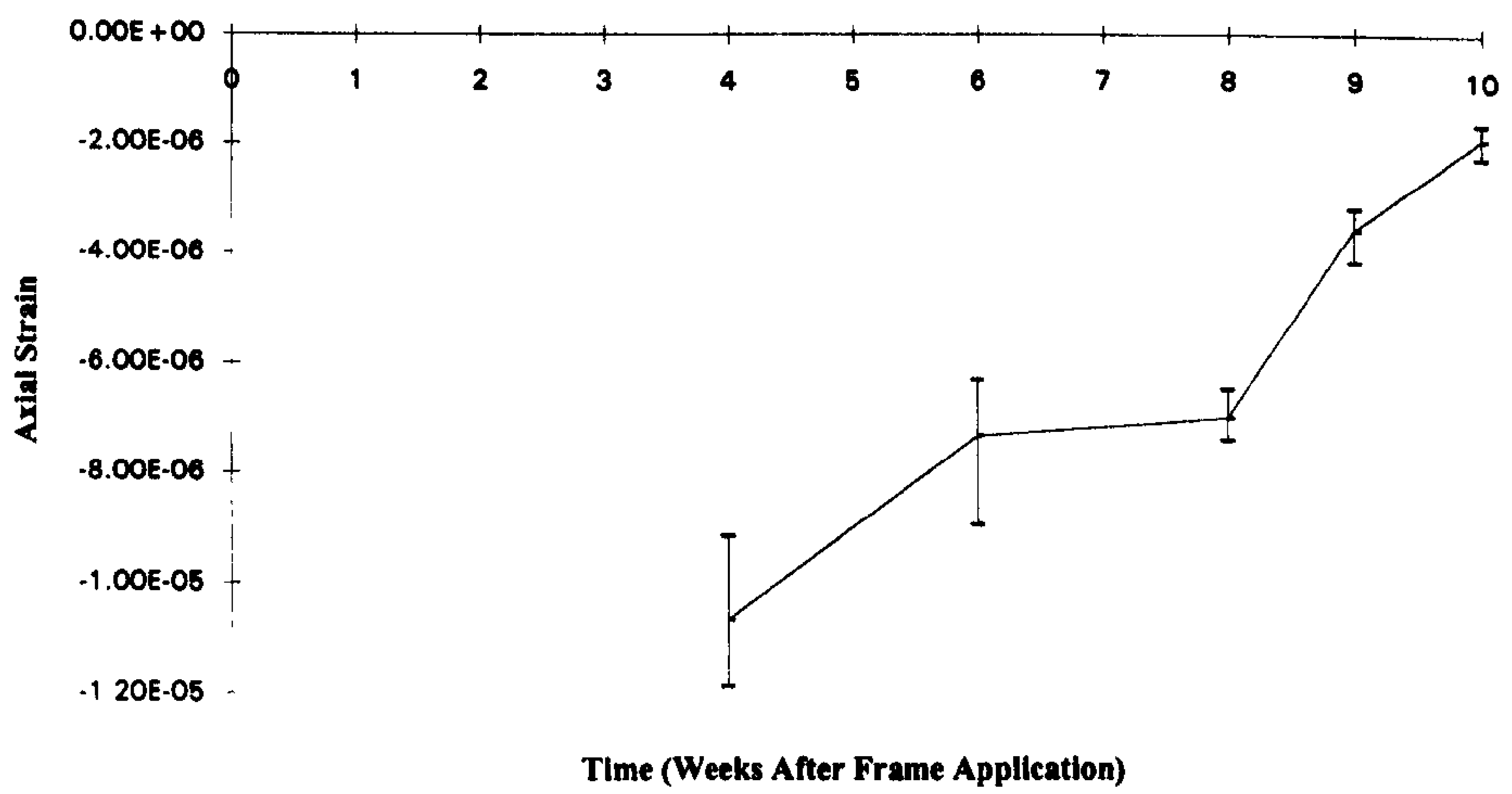
The results of the present study are shown as a series of graphs in figure 42. The graphs show axial strain as measured with the instrumented connecting rod, using the test protocol described in section 5.2, versus time after frame application; the mean and range of ten measurements are shown. Comparison of the graphs in figure 42 with that in figure 41 shows that the expected form of healing curve was only found in 3 patients; T3, figure 42c, T4, figure 42d, and, T8, figure 42h. However, in the majority of patients no meaningful pattern could be discerned from the sequential measurements; therefore, no attempt was made to fit curves to the datasets. Additionally it should be noted that patient T4 developed an atrophic non-union and so would not be expected to have a healing curve of similar form to patients T3 and T8, whos' fractures both achieved union. The data suggest that the assumption that a simple load sharing relationship exists between the fracture and the frame, may not be valid under conditions of Ilizarov external fixation. Given the greater geometrical complexity of the Ilizarov frame over, for instance, unaxial fixators, this is probably not surprising. One pattern which can be seen from many of the graphs in figure 42, is that the range of the measurements often decreases with time; this can be seen particularly clearly in the case of patient T5, figure 42e.



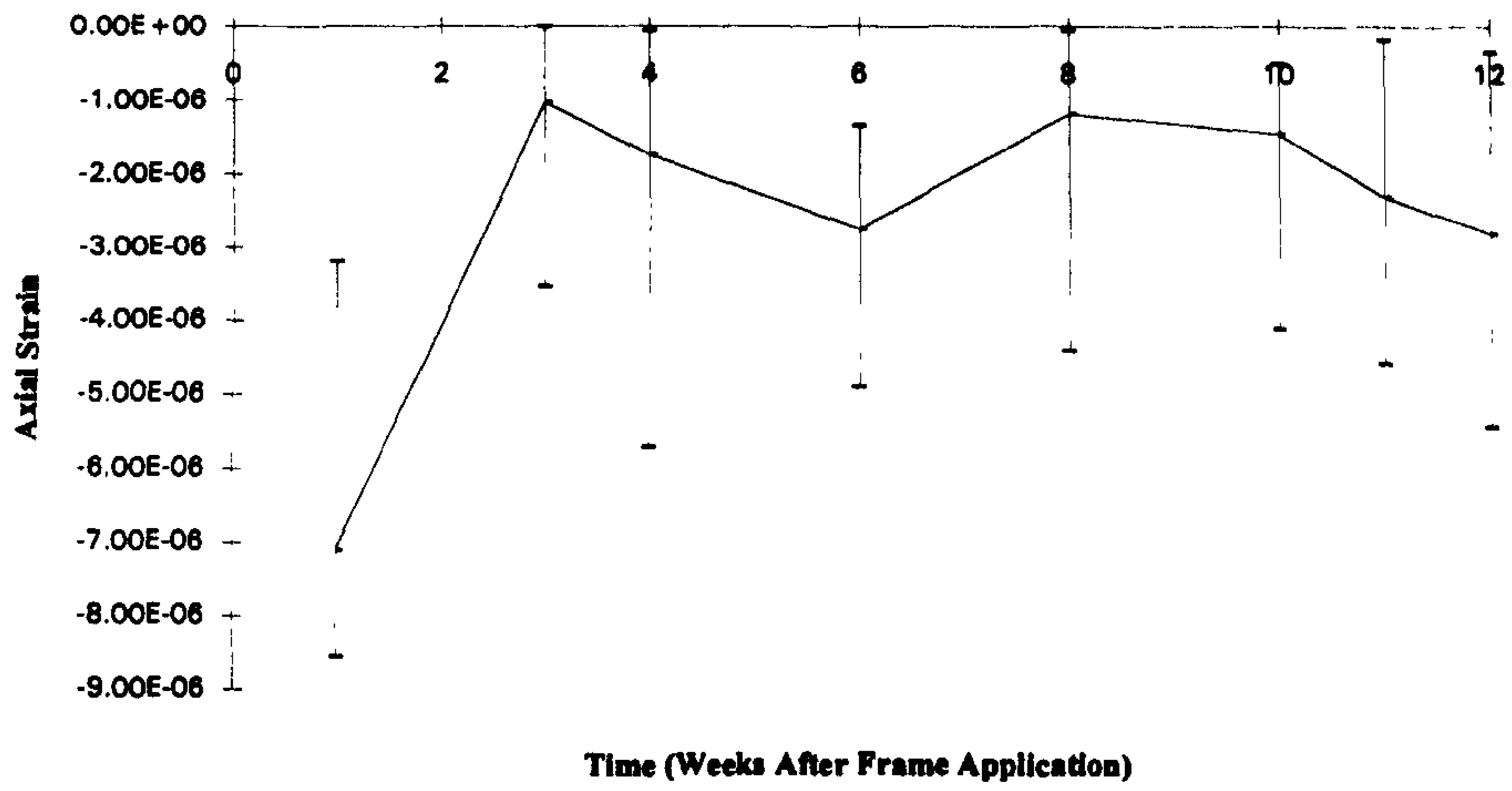
42a) Patient T1: Fracture judged clinically united by week 16.



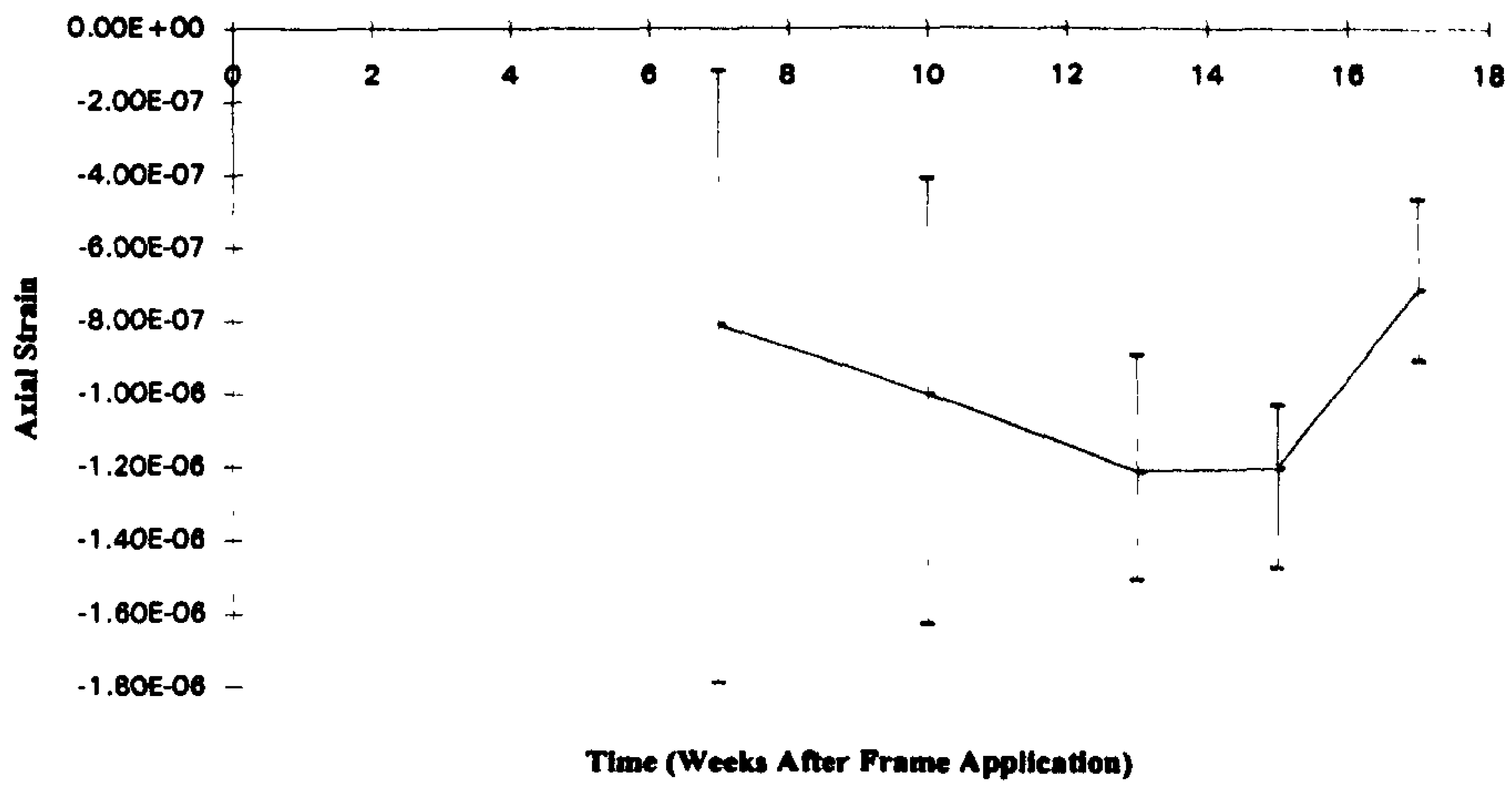
42b) Patient T2: Fracture judged clinically united by week 45.



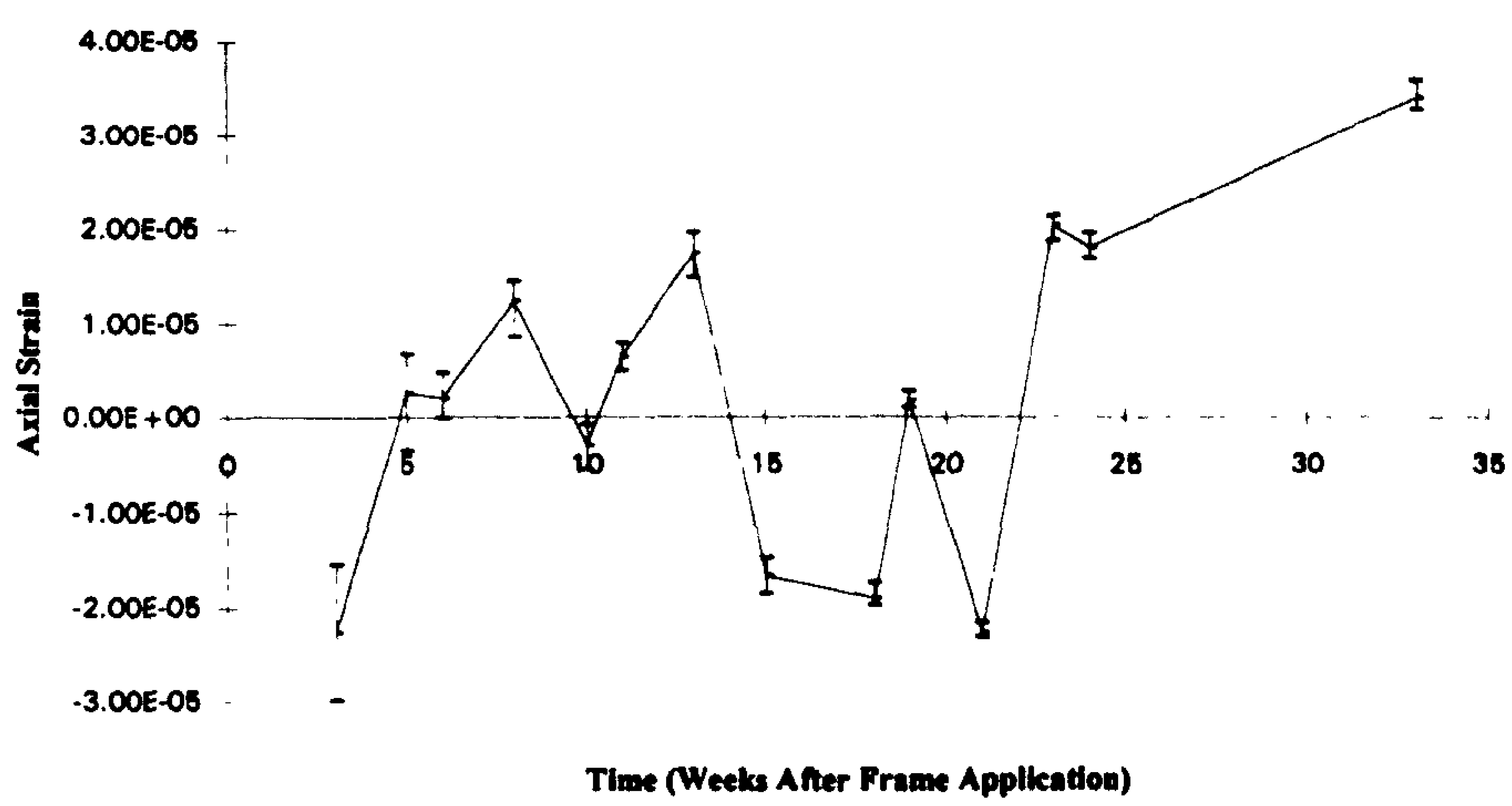
42c) Patient T3: Fracture judged clinically united by week 10.



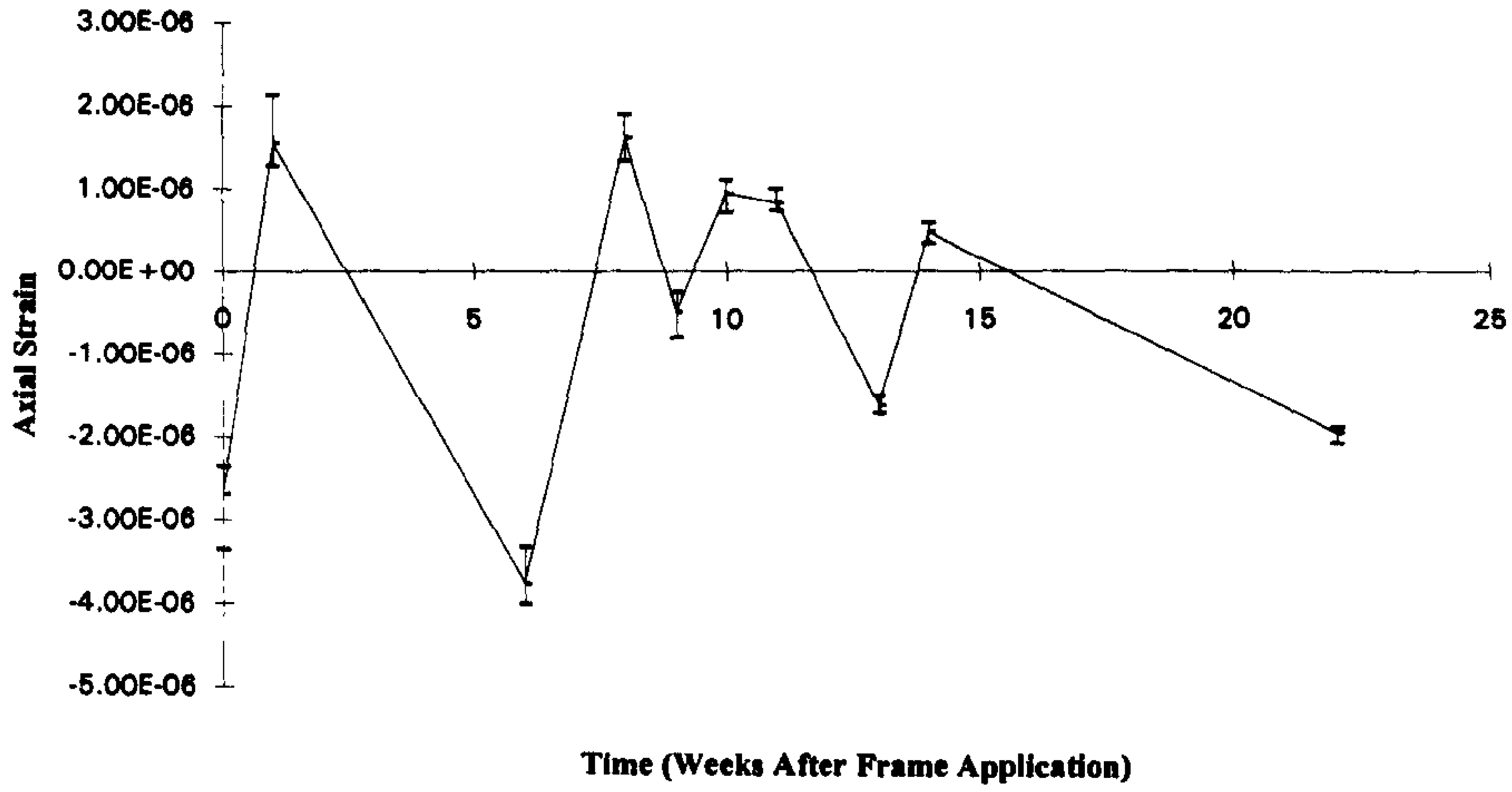
42d) Patient T4: Fracture had developed into an atrophic non-union by week 12.



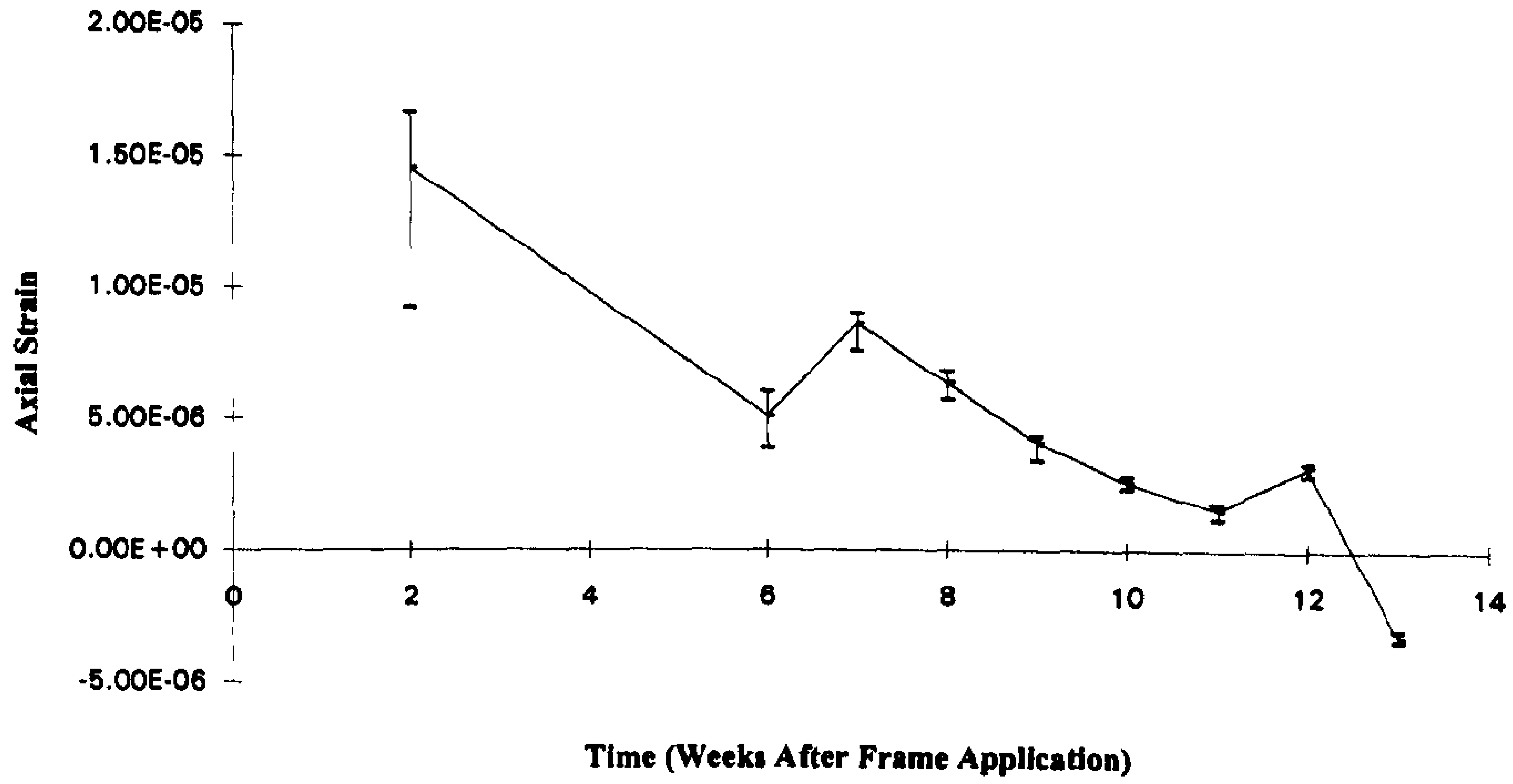
42e) Patient T5: Fracture judged clinically united by week 16.



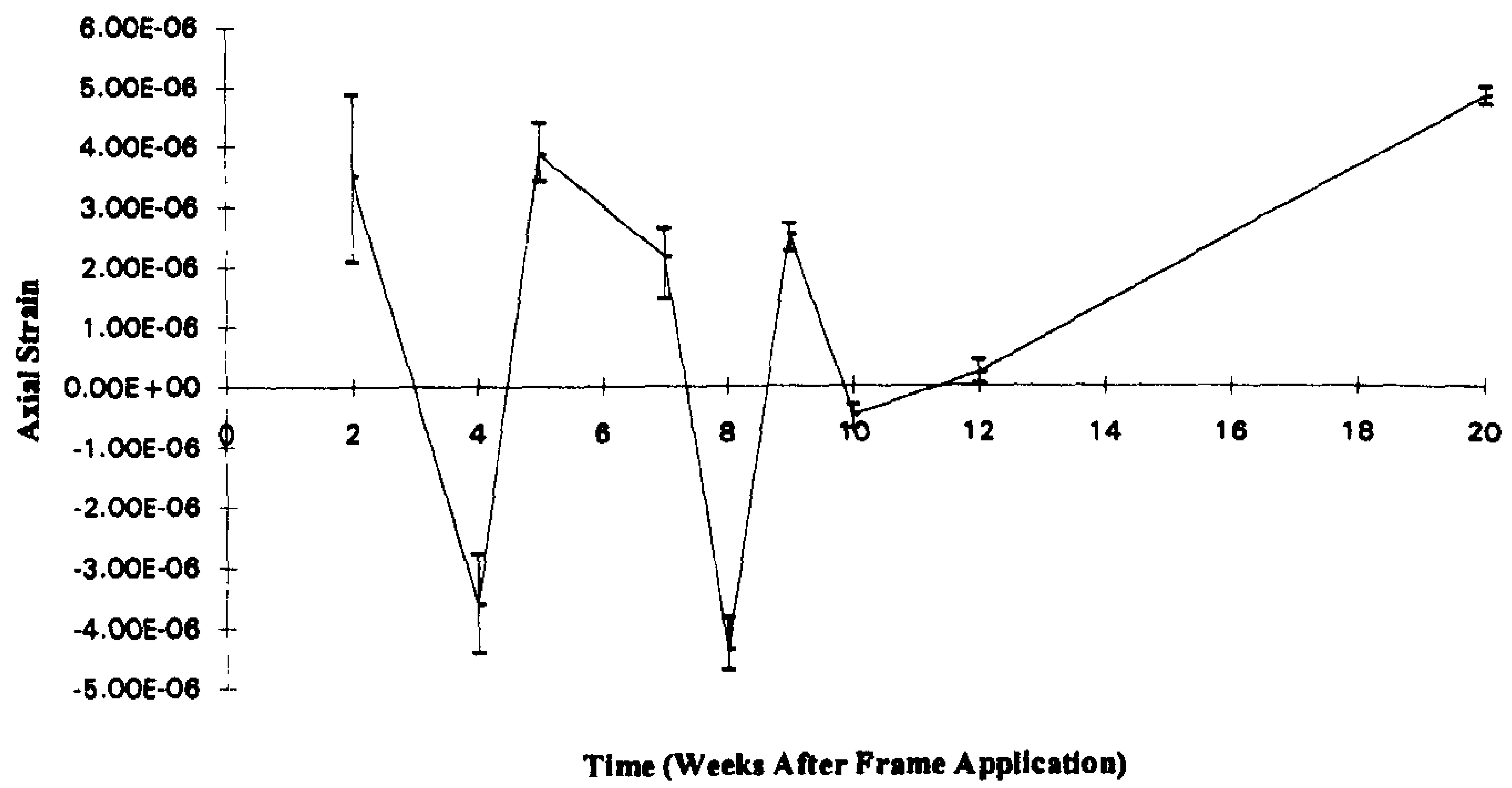
42f) Patient T6: Fracture had not achieved clinical union by week 33.



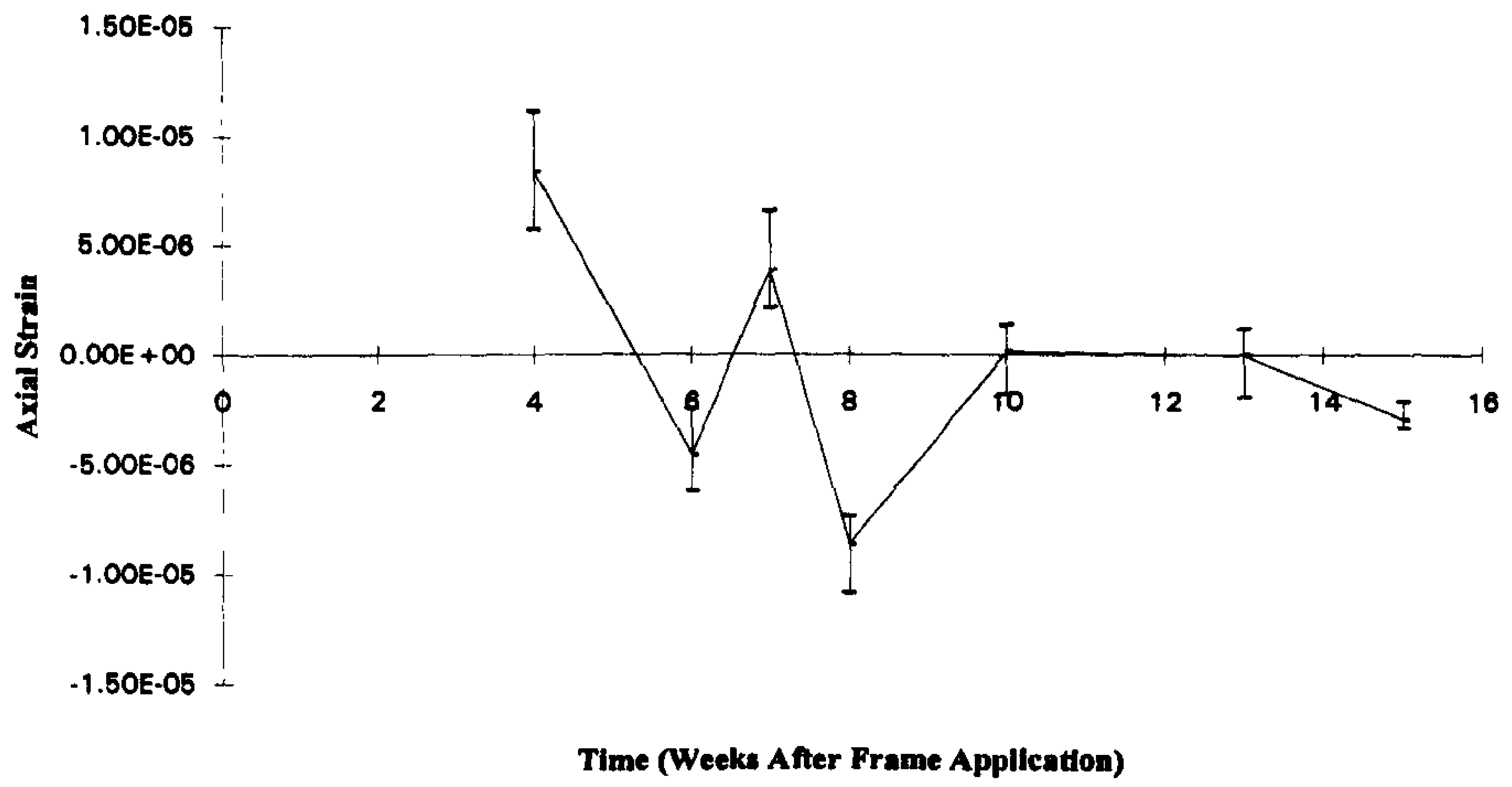
42g) Patient T7: Fracture judged clinically united by week 22.



42h) Patient T8: Fracture judged clinically united by week 13.



42i) Patient T9: Fracture judged clinically united by week 20.



42j) Patient F1: Fracture judged clinically united by week 16.

Figure 42 Axial strain versus time for: a) to i), patients T1 to T9 and, j), patient F1. The mean and range of the 10 measurements taken at each test session are shown.

To further investigate the relationship between the range of the sets of measurements and time, graphs of the standard deviation of axial strain versus time were plotted for the 10 patients included in the study. These are shown in figure 43; curves were fitted to the datasets using the Matlab™ software package (The Mathworks Inc., Natick, Massachusetts, United States of America). The general form of the curve used was:

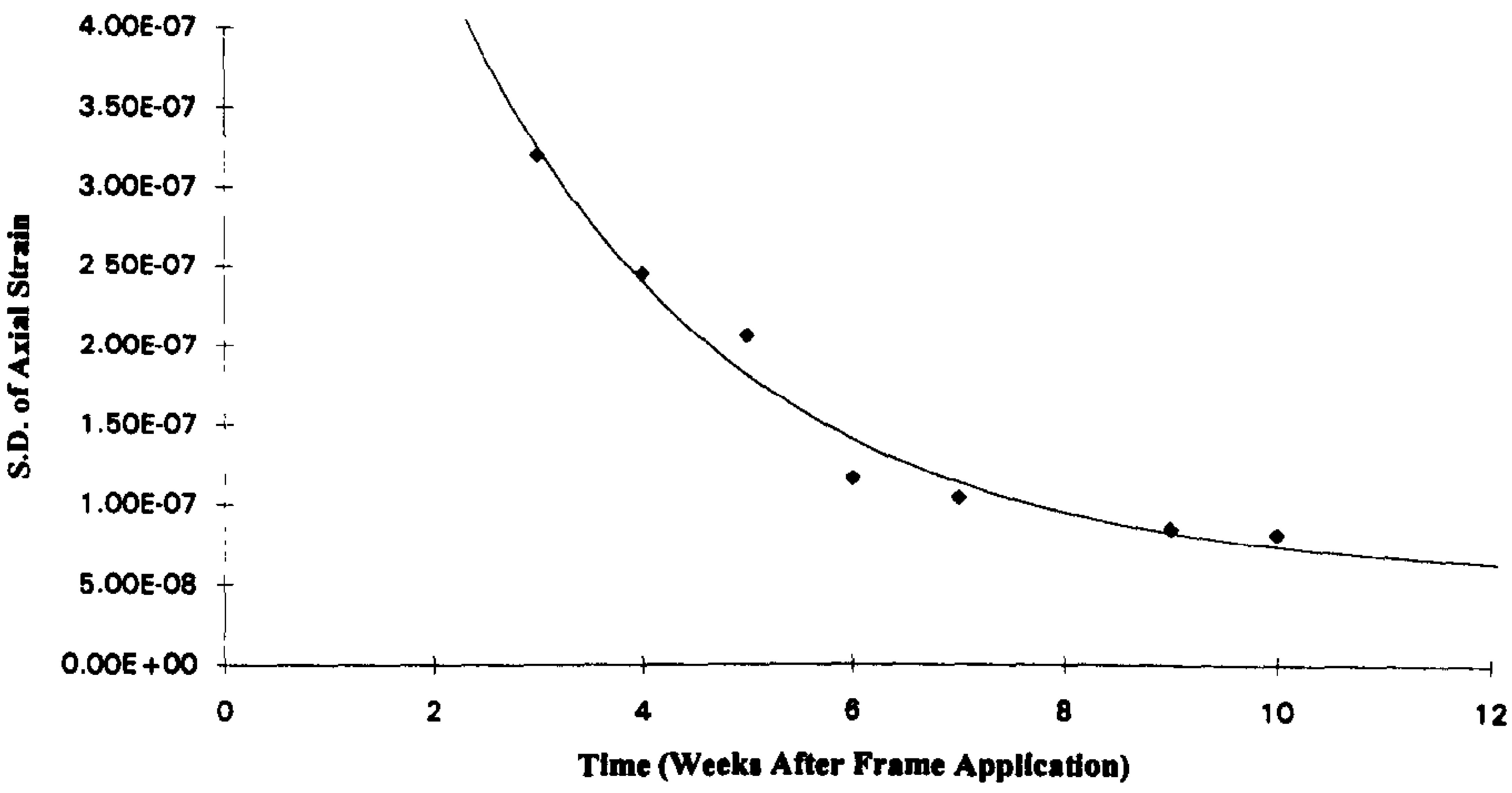
$$s = a + be^{-kt}$$

Where, s is the standard deviation of axial strain

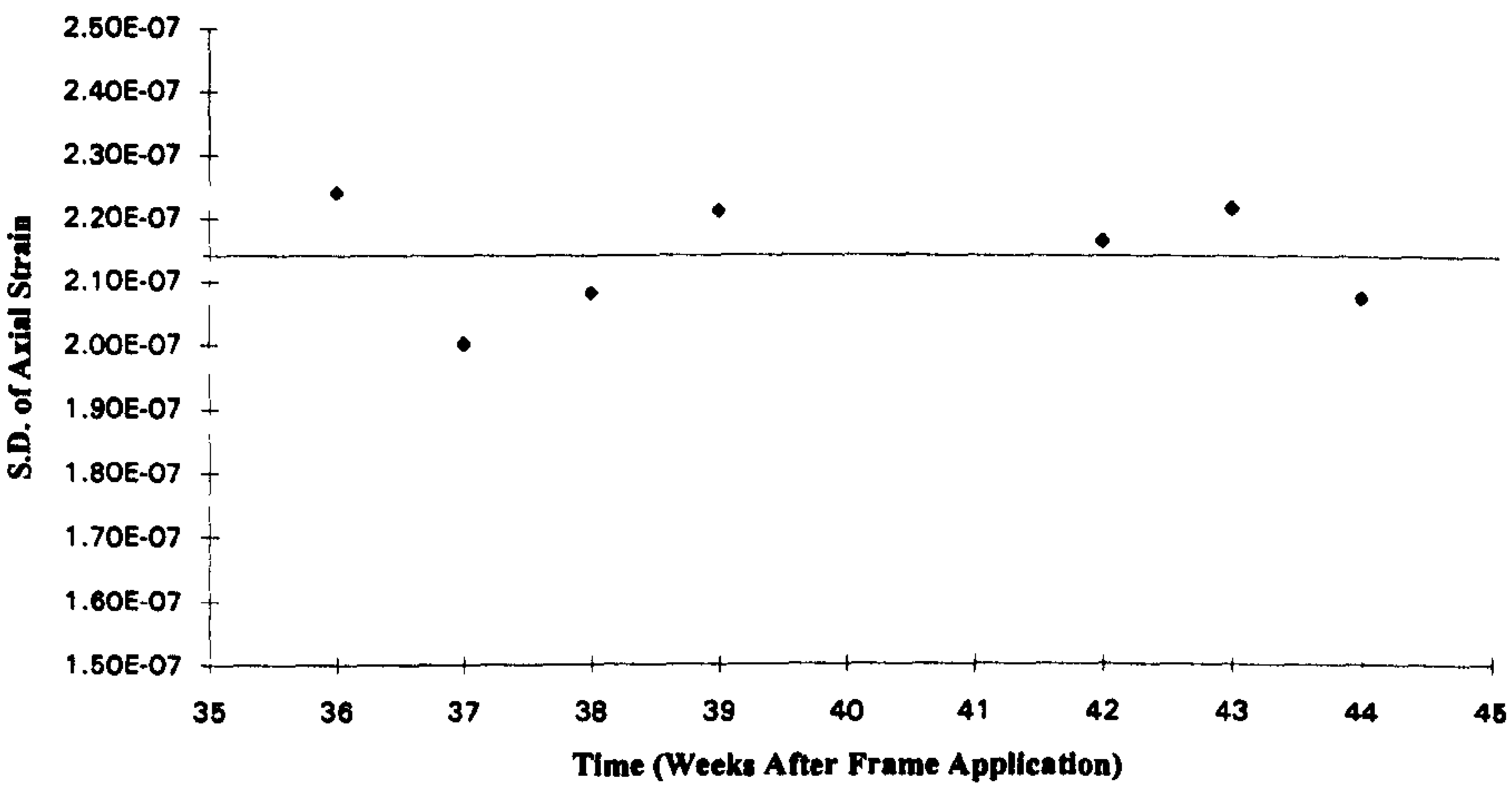
t is the time elapsed since frame application in weeks

a, b, and k are constants

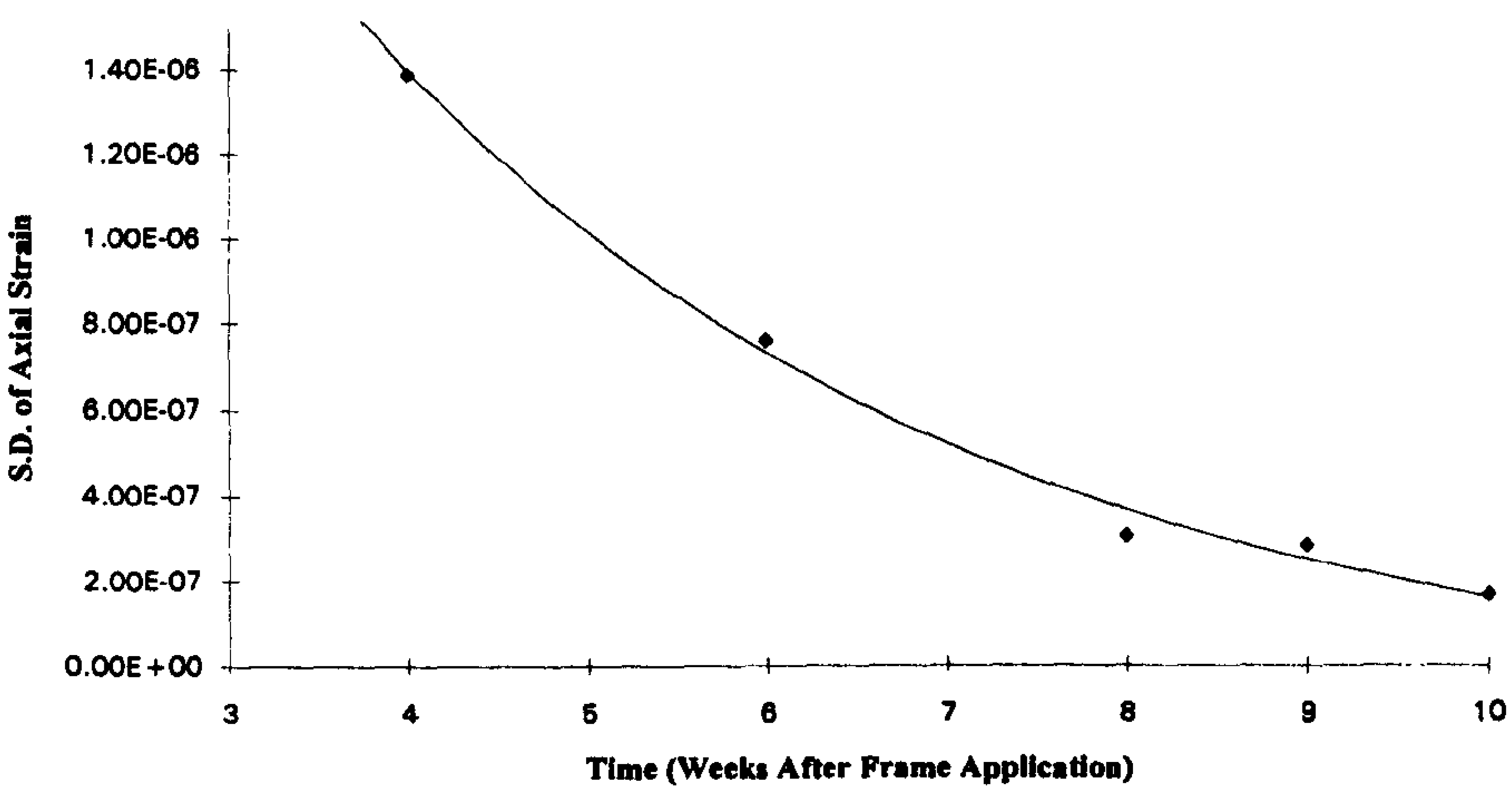
The values of the constants for the 10 curves are shown in table 17.



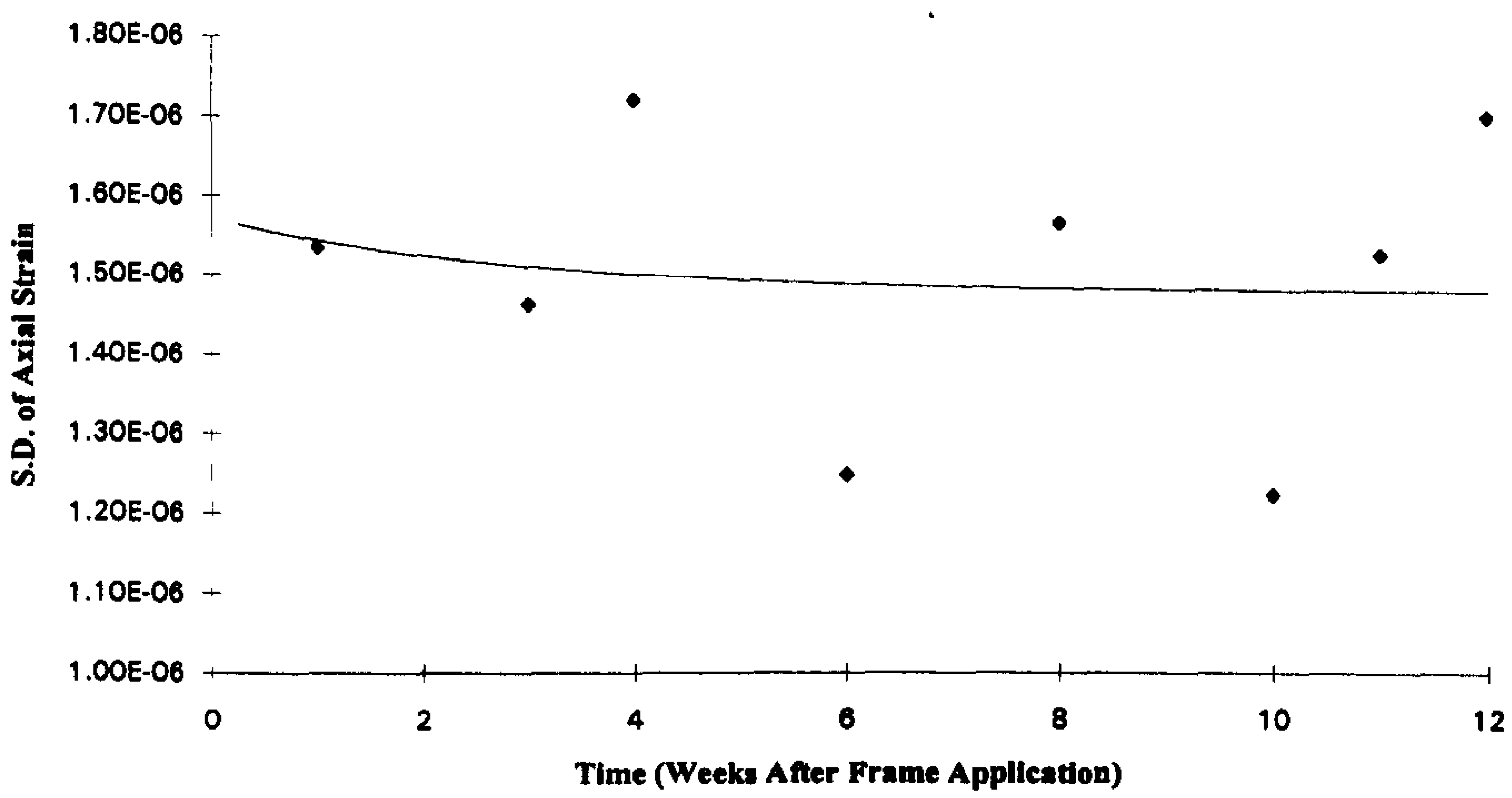
43a) Patient T1: Fracture judged clinically united by week 16.



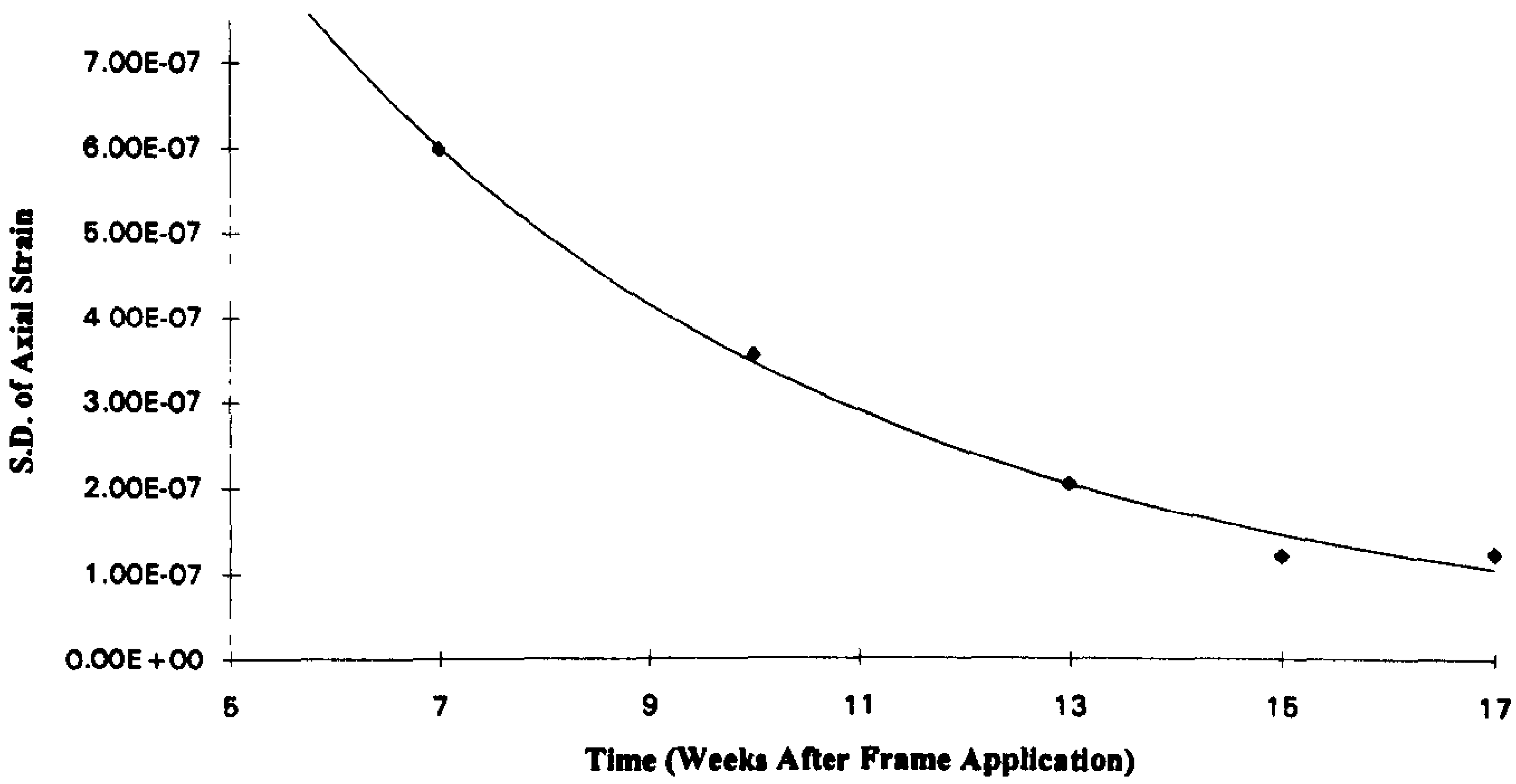
43b) Patient T2: Fracture judged clinically united by week 45.



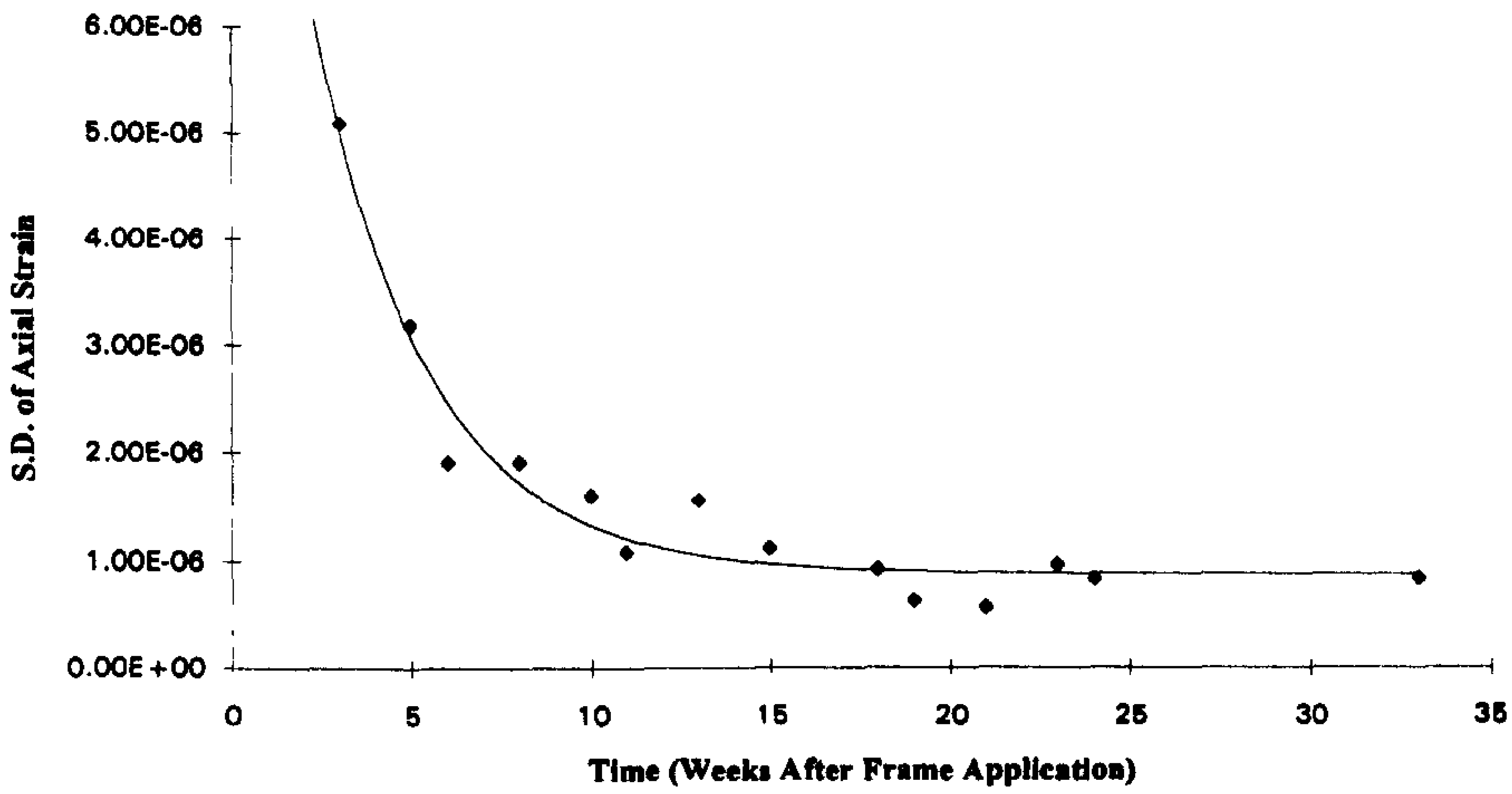
43c) Patient T3: Fracture judged clinically united by week 10.



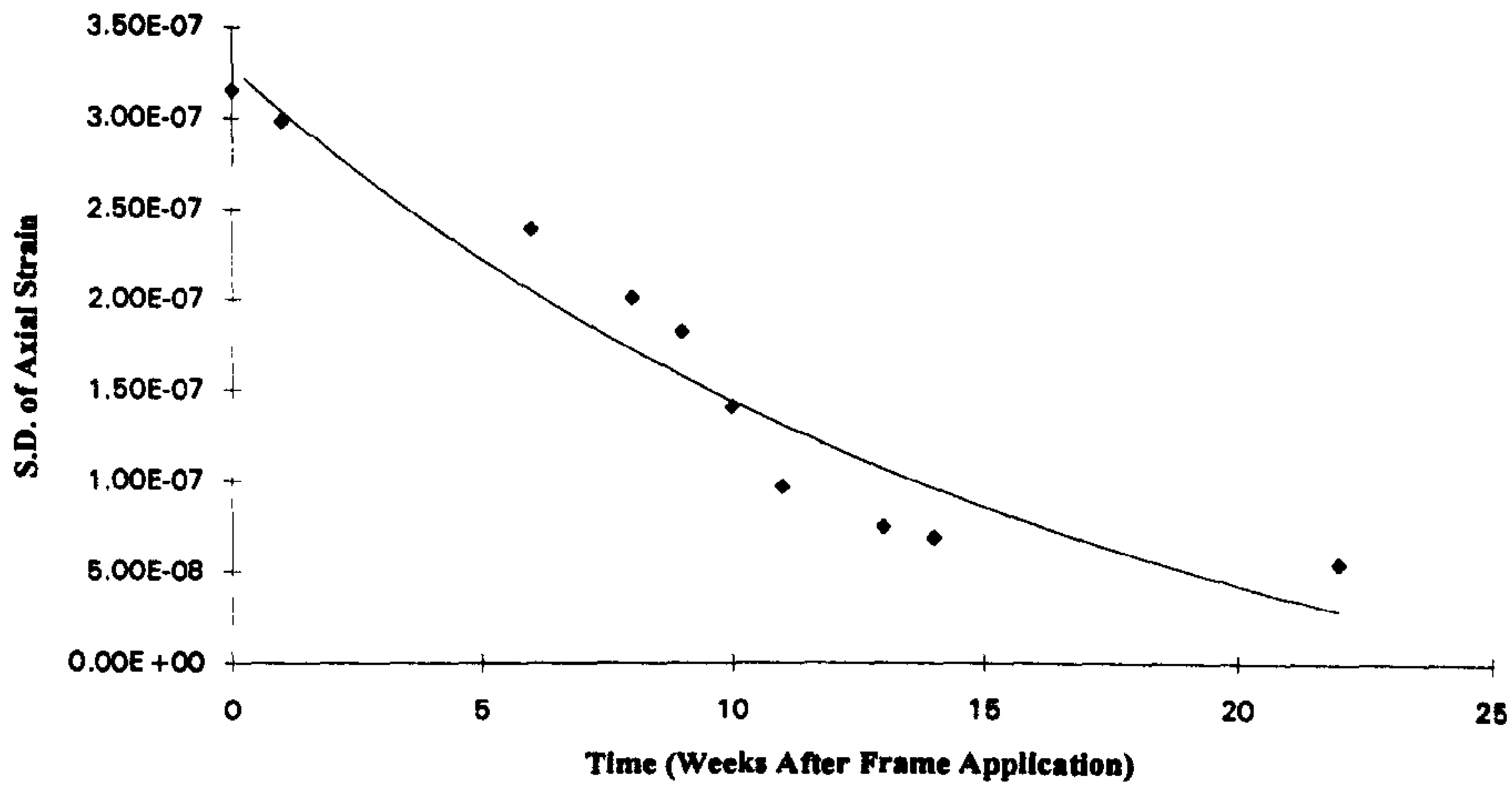
43d) Patient T4: Fracture had developed into an atrophic non-union by week 12.



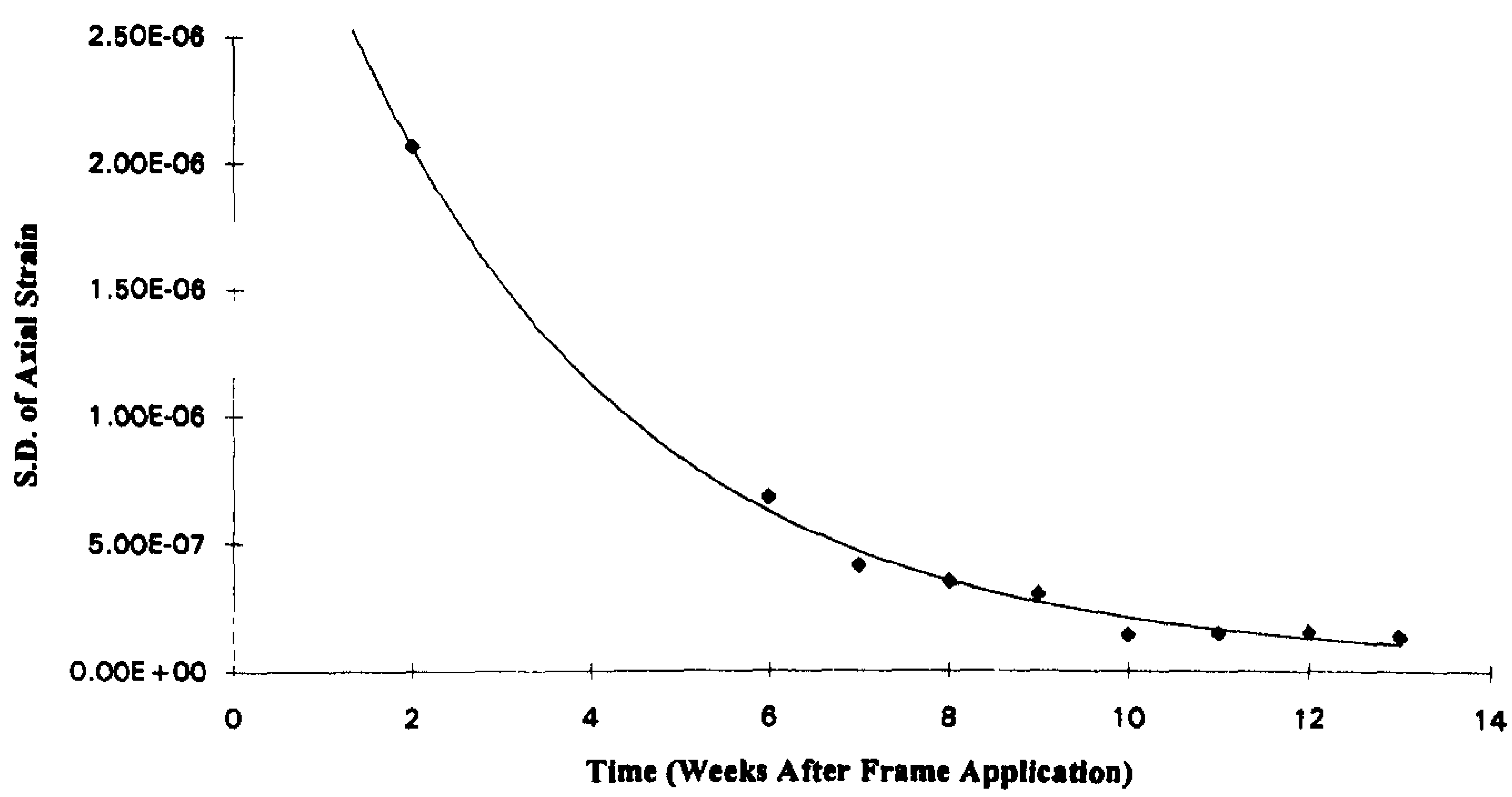
43e) Patient T5: Fracture judged clinically united by week 16.



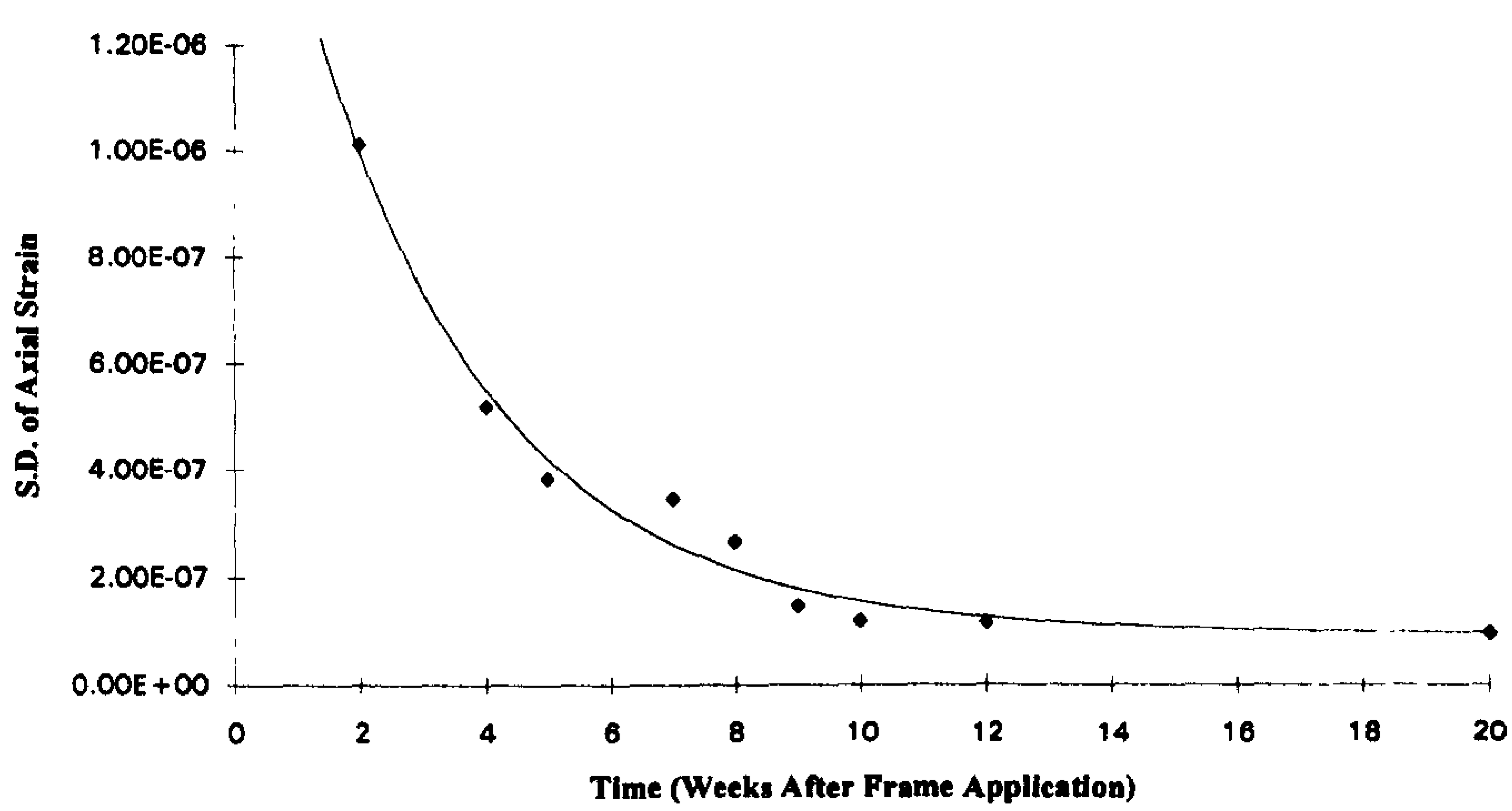
43f) Patient T6: Fracture had not achieved clinical union by week 33.



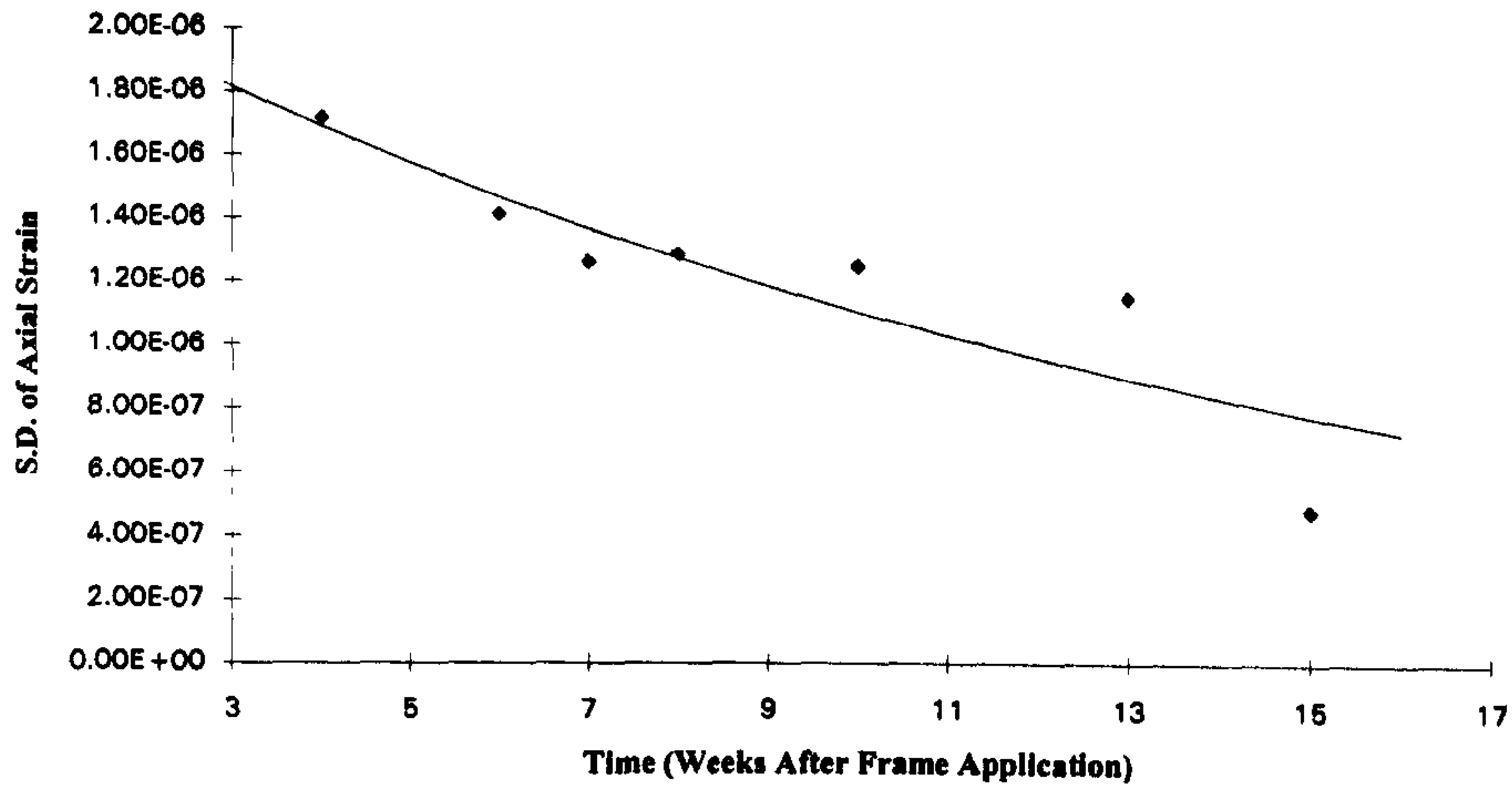
43g) Patient T7: Fracture judged clinically united by week 22.



43h) Patient T8: Fracture judged clinically united by week 13.



43i) Patient T9: Fracture judged clinically united by week 20.



43j) Patient F1: Fracture judged clinically united by week 16.

Figure 43 Standard deviation of axial strain versus time for: a) to i), patients T1 to T9 and, j), patient F1. 10 measurements were taken at each test session.

Table 17 Coefficients of the curves fitted to the datasets of patients T1 to T9, and F1. The curves had the general form $s = a + be^{-kt}$.

Patient Code	a	b	k
T1	5.49E-08	8.41E-07	3.79E-01
T2	2.14E-07	1.67E-06	2.98E-01
T3	-7.93E-08	4.93E-06	3.01E-01
T4	1.48E-06	9.49E-08	3.66E-01
T5	2.45E-08	2.24E-06	1.94E-01
T6	8.77E-07	1.08E-05	3.20E-01
T7	-8.23E-08	4.10E-07	5.93E-02
T8	4.29E-08	3.76E-06	3.11E-01
T9	9.52E-08	1.79E-06	3.42E-01
F1	1.82E-08	2.23E-06	7.21E-02

From the graphs, in figure 43, it can be seen that the curves provide reasonably close fits to all the datasets with the exception of patient T4, the patient who developed an atrophic non-union. The healing outcomes of the 10 patients included in the study will be briefly considered below with reference to the graphs in figures 42 and 43.

As a preliminary to the discussion it is worth noting two points. Firstly, the clinical assessment of fracture healing by the use of radiographs is an inherently subjective process, as has been discussed in section 2. It is also a discontinuous process which can only occur when the patient both, a) attends clinic and, b) is radiographed. Secondly, the general form of curve fitted to the standard deviation data was chosen because it is one which is often fitted to data on biological processes; it also appeared to fit the majority of the datasets. A different form of curve might have fitted some of the datasets better but, given the small sample size, it did not seem appropriate to use several forms of curve. To avoid excessive repetition, the term "rod strain" will be used to indicate: axial strain, as measured with the instrumented rod using the test protocol described in section 5.2.

Patient T1

The graph of rod strain versus time, figure 42a, does not have the form of a typical healing curve, *i.e.* the form of the curve shown in figure 41; if anything, rod strain appears to increase with time. The standard deviation of rod strain decreases with time; the curve fitted to the data, figure 43a, approaches its asymptotic value by week 12. The patient's fracture was radiographed at week 8 and week 16. At week 8 callus was forming; at week 16 the fracture was judged clinically united on the basis of the radiographs and it was noted that bone remodelling had begun. The latter observation suggests that the fracture had united prior to week 16. Fracture union could not have been predicted on the basis of the absolute values of rod strain in this case. However, the standard deviations of the sets of measurements appear to indicate progress towards union.

Patient T2

The graph of rod strain versus time, figure 42b, does not have the form of a healing curve; the magnitude of the strain is relatively low and the distribution of the points appears arbitrary. The curve fitted to the standard deviation of rod strain versus time, figure 43b, has a negligible gradient. The patient's fracture was radiographed at week 36 and next at week 45, when the fracture was judged clinically united. There was apparently little difference in the radiographic evidence of fracture union between weeks 36 and 45, and the decision regarding fracture union was based largely on the amount of time which had elapsed since the fracture began uniting. The standard deviation of rod strain appears to show little change between week 36 and week 44.

Patient T3

Figure 42c shows that the graph of rod strain versus time is similar to the expected healing curve; the graph had not, however, approached its asymptotic value by the time the fracture was judged united at week 10. The graph of standard deviation of rod strain versus time, figure 43c, shows a similar trend. Hence, both rod strain, and the standard deviation of rod strain, appear to indicate progress towards fracture union.

Patient T4

The graph of rod strain versus time, figure 42d, appears similar to a healing curve but the majority of the drop in the magnitude of rod strain occurs between week 1 and week 3. The curve fitted to the standard deviation of rod strain versus time data has a relatively low gradient and approaches its asymptotic value by week 12. By reference to table 17, it can be seen that the asymptote of the curve, constant a, is considerably higher than the asymptotes of the curves fitted to the other patients' data; similarly the difference between the value of standard deviation at week 0 and its asymptotic value, *i.e.* the value of constant b, is much lower than those for the other curves. The patient's fracture was radiographed at 5 weeks and at 12 weeks. At 5 weeks healing apparently appeared to be progressing normally but by week 12 a non-union was developing. In this case, rod strain would appear to indicate progress towards fracture union whereas, the standard deviation of rod strain appears to indicate little progress.

Patient T5

The shape of the graph of rod strain versus time for this patient, figure 42e, does not conform to that of a typical healing curve; rod strain initially increases and then falls. The standard deviation of rod strain can be seen to gradually decrease with time, figure 33e. From the radiographic evidence the healing of this patient's fracture apparently progressed normally; the fracture was judged clinically united by week 16. Fracture union could not have been predicted on the basis of the absolute values of rod strain in this case. However, the standard deviation of rod strain appears to indicate progress towards union.

Patient T6

The graph of rod strain versus time, figure 42f, has a superficial resemblance to a healing curve but there are many reversals. The curve fitted to the standard deviation of rod strain versus time data approaches its asymptotic value by week 18. The patient's fracture was radiographed at weeks 7, 15, and 31. By week 7, callus material had begun to form in one quadrant of the fracture gap; by week 15, the callus had bridged the gap in that quadrant. By week 31, the callus in the quadrant had developed into a buttress of new bone but the fracture gap was still clearly visible in the other quadrants. The standard deviation of rod strain appears to indicate progress towards union in this case. However, it should be noted that the asymptotic value of the curve fitted to the data, *i.e.* constant *a,* table 17, was relatively high and was exceeded only by that of the curve fitted to the data of patient T4, who developed a non-union.

Patient T7

No meaningful pattern can be discerned from the graph of rod strain versus time for this patient, figure 42g. The magnitude of the standard deviation of rod strain gradually decreases with time, figure 43g. From the radiographic evidence the healing of this patient's fracture apparently progressed normally; the fracture was judged clinically united by week 22. The progress of fracture healing could not have been monitored using the values of rod strain in this case; the standard deviation of rod strain appears to indicate progress towards union.

Patient T8

The shape of the graph of rod strain versus time, figure 42h, is similar to that expected of a healing curve, though, there are a couple of reversals. The standard deviation of rod strain gradually decreases with time, but the curve fitted to the data, figure 43h, had not approached its asymptotic value by week 13 when the fracture was judged clinically united. In this case it would appear that both the values of rod strain and their standard deviations could be used to monitor the progression of fracture healing.

Patient T9

No meaningful pattern can be discerned from the graph of rod strain versus time for this patient, figure 42i. The magnitude of the standard deviation of rod strain gradually decreases with time, figure 43i. The curve fitted to data approaches its asymptotic value by week 20 when the fracture was judged clinically united. The standard deviations of the sets of measurements of rod strain appear to indicate progress towards union.

Patient F1

No meaningful pattern can be discerned from the graph of rod strain versus time for this patient, figure 42j. The magnitude of the standard deviation of rod strain gradually decreases with time, figure 43j. The curve does not fit the data so well in this case; it does not approach its asymptotic value by week 16 when the fracture was judged clinically united. The standard deviations of the sets of measurements of rod strain appear to indicate progress towards union.

To summarise, in this study, measurements of relative axial strain indicated that normal healing was progressing in only 3 patients, T3, T4, and T8; in one of these patients, T4, normal healing was not progressing. The measurements failed to indicate that normal healing was progressing in patients T1, T5 - T7, T9, F1 and, possibly, T2. This suggests that the assumption that a simple load sharing relationship exists between the fracture and the frame, *i.e.* the basis of relative stiffness monitoring techniques, may not be valid under conditions of Ilizarov external fixation.

However, the standard deviations of each set of measurements appeared to indicate that normal healing was progressing in 8 patients, T1, T3, T5 - T9, and F1; though in one of these patients, T6, only a partial union was achieved. They also appeared to indicate that healing had stopped in patient T4, where it had, and patient T2, where it possibly had. These results suggest that the standard deviation of a set of relative stiffness measurements may be a better indicator of fracture healing than the measurements themselves; this will be considered in the next section.

5.4 Implications of the Results and Suggestions for Further Work

In the study described in this section, the standard deviation of each set of 10 relative stiffness measurements was found to decrease with increased duration of healing. To the author's knowledge this observation has not been specifically commented on in previous studies which have used relative stiffness measurements to monitor fracture healing; there are probably two reasons for this.

Firstly, the majority of previous studies have involved uniaxial fixation. The assumption that a simple load sharing relationship exists between the fracture and fixator is more likely to be valid under conditions of uniaxial fixation because loads applied to the fracture-fixator system are shared between the fracture and a single longitudinal support member. By comparison, under conditions of Ilizarov external fixation the load applied to the fracture-frame system is shared between the fracture and as many as 6 longitudinal support members.

Secondly, in order to observe a decrease in standard deviation it is necessary to conduct several repeat measurements at each test session. The protocol for the Italian Maggiore della Carità study called for each test, *i.e.* flexion-extension, bending, and walking tests, to be repeated only once at each session (**104**). The influential Richardson-Cunningham group repeated measurements 3 times per test session and so may not have observed the effect (**52, 59, 60, 75, 76, 107**); Jørgensen (**58**) and Nishimura (**78**) do not state how many repeat measurements were conducted.

To the present author's knowledge, only one previous study repeated relative stiffness measurements 10 times each session, as in the present study; this was the study by Kristiansen and Borgwardt described above (57). Kristiansen and Borgwardt do not specifically comment on the standard deviation of rod strain measurements decreasing with increased duration of healing. However, they present healing curves of 3 for the 7 patients included in the study; from these, it can be seen that the range rod strain measurements tends to decrease with increased duration of healing in much the same manner as was seen in the present study.

There are several factors which could give rise to a decrease in the standard deviation of each set of readings with the passage of time. The patients could possibly "learn" to perform the tests with a greater repeatability, though, given the precautions taken to conduct the tests under identical conditions, this seems unlikely. Alternatively, the effect might be caused by progressive yielding of some of the frame components; though, if this were the case a decrease in standard deviation would be expected in all patients regardless of healing outcome; no decrease was observed in patients T2 and T4.

Therefore, given that the graphs in figure 43 are in reasonable agreement with the clinical and radiographical assessments of fracture healing, it seems likely that the decrease in standard deviation reflects some aspect of the biomechanical environment at the fracture gap. Based partly on the data from patient T6, who's graph of standard deviation of rod strain, figure 43f, approaches its asymptotic value even though only a partial union had been achieved, the present author suggests that the decrease in standard deviation may indicate a decrease in micro-movement at the fracture gap.

The hypothesis is that the pattern of strain induced in an external frame when a load is applied to the fracture-frame system is a function of the position of the bone ends.

In a newly stabilised fracture, shear movements can occur between the bone ends that give rise to a large range of strain patterns in the frame. As the fracture heals, and its cohesion grows, the amplitude of such movements tends to zero and so the strain induced in the frame tends to a single pattern. Therefore, for a given load, the standard deviation of a set of measurements of strain at a point on the frame will decrease as healing progresses.

To confirm the above hypothesis it would be necessary to measure strain in all the connecting rods of a frame and correlate the strain patterns obtained with measurements of interfragmentary motion. Connecting rod strain could be easily measured using devices similar to those used in the present study. A methodology for measuring interfragmentary motions induced by weight bearing in human studies has been developed by Sarmiento *et al.* (27).

To summarise, in this study relative axial stiffness measurements *per se* were found to be a poor indicator of fracture healing in the majority of patients. This may be because the basic assumption of a simple load sharing relationship between the fracture and the fixator, *i.e.* the basis of the relative stiffness monitoring techniques, is not valid for Ilizarov fixation were loads applied to the fracture-frame system may be shared between the fracture and as many as 6 longitudinal support elements. Specifically, the problem appears to be that the load bypass, *i.e.* the proportion of the load carried by the frame as opposed to the fracture, is not shared amongst the rods in constant proportions. It is suggested that this may arise from micro-movements of the bone ends. The standard deviations of the sets of measurements, however, proved to be a useful indicator that fracture healing was progressing. It is suggested that, with further development, the technique could provide a useful means of monitoring fracture healing under conditions of Ilizarov external fixation.

CHAPTER 6. Conclusions

The work described in this dissertation had three primary objectives. Firstly, to investigate the significance of the plastic deformation which occurs in the tensioned fine wires on the long-term performance of the original Ilizarov frame. Secondly, to investigate the biomechanics of the modified Ilizarov frame and the contributions made to the axial compression stiffness by the main structural components. Thirdly, to investigate methodologies for monitoring fracture healing using measurements of fracture axial stiffness. Achieving these three objectives involved three separate, but related, studies. The main findings and achievements of these three studies are briefly summarised in section 6.1; recommendations for further work are given in section 6.2.

6.1 Summary of Research Findings

The original Ilizarov frame

The tensioned fine wires used in the original Ilizarov frame undergo significant plastic deformation when they are first exposed to moderate loads, such as those imposed by functional weight bearing. The plastic deformation causes a reduction in wire tension, resulting in a reduction in overall frame stiffness and, hence, compromises the frame's ability to resist shear motion and high amplitude axial motion. After a few cycles of loading, at a constant level of load, the amount of plastic deformation occurring during each loading cycle becomes relatively small; there are two reasons for this. Firstly, the wire material work hardens and secondly, the residual tension in the wire has been reduced as a result of the plastic deformation caused by previous cycles of loading. Within a few cycles, yielding only occurs at the bends in the wire, *i.e.* adjacent to the clamps and the bone. The magnitude of the stress in these regions is a function of the stress induced in the wire by the residual tension and the stress induced in the wire upon deflection. Eventually the residual tension in the wire is reduced to a level where the maximum stress reached in these areas during loading no longer exceeds the yield point of the work hardened material. In the case of a 180 mm long wire with a diameter of 1.8 mm and an initial pretension of 981 N, yielding will cease when the residual tension has fallen to about 785 N, or about 80 % of the pretension.

The yielding of the tensioned fine wires in the original Ilizarov frame was not perceived as a problem at the Kurgan All-Union Centre for Restorative Traumatology and Orthopaedics, where it was developed, because the patients remained as in-patients throughout the course of their treatment and received daily clinical supervision. In such an environment it is presumably relatively easy for the surgeon to make regular, responsive, minor adjustments to the frame, such as re-tensioning of the wires. In the West, however, patients treated with the Ilizarov technique tend to be treated as out-patients and may only receive clinical supervision once every 4 to 6 weeks. Therefore, the use of hybrid Ilizarov frame, which only derives part of its stiffness from fine wires but retains the some of the beneficial non-linear axial stiffness of the original, would seem appropriate.

The modified Ilizarov frame

The consolidation of immature callus material into mature callus with a typical lamellar structure is favoured by the imposition of a normal loading regime, albeit of a lower than normal magnitude. In adult long bones the predominant loading regime consists of axial and tensile stresses approximately parallel to the long axis of the bone. The study of the modified frame showed that the practice of de-stabilising frames by the removal of 1 or 2 of the connecting rods actually has a relatively small effect on the axial stiffness of the frame. Removing 2 rods from a frame in which there are 6, for instance, will only reduce the axial stiffness of the frame by about 4

%. However, the removal of rods will probably have a more significant effect on the torsional and bending stiffness of the frame. Therefore, the mechanical environment imposed on the consolidating callus may be very different from the normal loading regime for the bone. De-stabilising of frames by the release of one, or more, of the pins would have a greater effect on the axial stiffness and probably a lesser effect on the bending and torsional stiffnesses.

The study of the modified frame also demonstrated that in frames which use half pins for the support of bone fragments, the displacement of the bone ends in response to an axial load usually has a shear, as well as an axial, component. The shear component arises because the half pins act as cantilevers and the bone ends rotate about a point defined by the frame configuration. In a frame which is symmetrical about a plane through the centre of the fracture gap perpendicular to the long axis of the frame, no shearing would occur; however, this is a hypothetical exception. The tendency for shearing to occur is greatest in frames applied to fractures near the distal and proximal ends of long bones. In theory, the shearing could be eliminated by optimising the radial spacing of the half pins. In practice, this is likely to be precluded by other considerations, such as soft tissue transfixion.

Another significant aspect of the mechanical behaviour of frames in which half pins are used to support bone fragments which was demonstrated by the study, is that under axial compression a non-uniform stress is usually imposed on material in the fracture gap, or the bone ends themselves if they come into contact; this effect is independent of the symmetry of the frame and will always occur. As both these effects appear to have significant implications on healing outcomes it is suggested that they should be investigated further.

The use of axial stiffness measurements to monitor fracture healing

On the basis of the results of animal studies and theoretical considerations it would appear that both axial and bending stiffness can be used as indicators of the normal progression of fracture healing. However, in the later stages of healing, tensile axial stiffness may be a better indicator of fracture strength than bending stiffness which is liable to overestimate the strength of the fracture. An *in-vitro* study showed that direct measurement of the tensile axial stiffness of a healing fracture may be possible *in-vivo* with the frame *in-situ*. Unfortunately, it was not possible to confirm this.

The applicability of relative stiffness measurements *per se* to monitor fracture healing under conditions of circular external fixation would appear to be limited. This may be because the basic assumption of a simple load sharing relationship between the fracture and the fixator, *i.e.* the basis of the relative stiffness monitoring techniques, is not valid for Ilizarov fixation. Specifically, the problem appears to be that the load bypass, *i.e.* the proportion of the load carried by the frame as opposed to the fracture, is not shared amongst the multiple rods in constant proportions. Previous studies have, in the main, been confined to uniaxial fixation where the load applied to a fracture-frame system is shared between the fracture and a single longitudinal support member.

The standard deviations of the sets of relative stiffness measurements, however, proved to be a useful indicator of the progression of fracture healing in the patients included in the *in-vivo* study. It is not clear why this should be so but it is suggested that the effect may be caused by a decrease in micro-movement at the fracture site as healing progresses. It is suggested that the effect should be further investigated as it could provide a useful means of monitoring fracture healing under conditions of Ilizarov external fixation.

6.2 Recommendations for Further Work

The original Ilizarov frame

1) The present study has shown the plastic deformation of the tensioned fine wires in response to loads imposed by functional weight bearing leads to a gradual reduction in frame stiffness and that re-tensioning of the wires only temporarily restores the original stiffness. Therefore, there is a requirement for further study to establish the magnitude and frequency of loads applied to the frame by patients during activities of daily living (ADLs).

2) Another area which should be considered is the effect of loads induced in the frame by distraction osteogenesis; such loads are likely to be much higher than those imposed on the frame by the patient during ADLs.

The modified Ilizarov frame

The present study demonstrated that in frames which use half pins for bone support the displacement of the bone ends in response to an axial load generally has a shear as well as an axial, component and, hence, a non-uniform stress is applied to the material in the fracture gap. As this effect appears to have significant implications on the healing outcome, it is suggested that it should be investigated further.

The use of axial stiffness measurements to monitor fracture healing

In the present study, relative axial stiffness measurements *per se* were found to be a poor indicator of fracture healing under conditions of Ilizarov external fixation. The standard deviations of the sets of measurements, however, proved to be a useful indicator that fracture healing was progressing. Therefore, it is recommended that:

1) The hypothesis developed in section 5.4 should be tested.

2) A larger scale clinical trial of the technique described in sections 4.4 and 5 should be conducted.

References

1 **Taylor, D.** Bone maintenance and remodeling: A control system based on fatigue damage. *J. Orthop. Res.,* 1997, **15**, 601-606.

2 **Wolff, J.**, trans. **Maquet, P.** and **Furlong, R.** *The law of bone remodelling.* Berlin, Springer, 1986.

3 **Rubin, C., Gross, T., Qin, Y., Fritton, S., Guilak, F.** and **McLeod, K.** Differentiation of the bone-tissue remodelling response to axial and torsional loading in the turkey ulna. *J. Bone Jt. Surg,* 1996, **78A,** 1523-1533.

4 **Lanyon, L. E.** and **Bourn, S.** The influence of mechanical function on the development and remodeling of the tibia. *J. Bone Jt. Surg,* 1979, **61A,** 263-273.

5 **Cowin, S.C.** Bone stress adaption models. *J. Biomech. Eng.*, 1993, **115**, 528-533.

6 **Lanyon, L. E.** and **Baggott, D. G.** Mechanical function as an influence on the structure and form of bone. *J. Bone Jt. Surg.,* 1976, **58B,** 436-443.

7 **Weinreb, M., Patael, H., Preisler, O.** and **Ben-Shemen, S.** Short-term healing kinetics of cortical and cancellous bone osteopenia induced by unloading during the reloading period in young rats. *Virchows Arch.*, 1997, **431**, 449-452.

8 **Roer, R.D.** and **Dillaman, R.M.** Bone growth and calcium balance during simulated weightlessness in the rat. *J. Applied Physiol.*, 1990, **68**, 13-20.

9 **Chao, E. Y. S., Aro, H. T., Lewallen, D. G.** and **Kelly, P. J.** The effect of rigidity on fracture healing in external fixation. *Clin. Orthop.,* 1989, **241**, 24-35.

10 **Carter, D. R., Blenman, P. R.** and **Beaupré, G. S.** Correlations between mechanical stress history and tissue differentiation in initial fracture healing. *J. Orthop. Res.,* 1988, **6**, 736-748.

11 **Goodship, A. E., Watkins, P. E., Rigby, H. S.** and **Kenwright, J.** The role of fixator frame stiffness in the control of fracture healing. An experimental study. *J. Biomechanics*, 1993, **26**, 1027-1035.

12 **Gilbert, J. A., Dahners, L. E.** and **Atkinson, M. A.** The effect of external fixation stiffness on early healing of transverse osteotomies. *J. Orthop. Res.*, 1989, **7**, 389-397.

13 **McRae, R.** *Practical fracture treatment.* London, Churchill Livingstone, 1981.

14 **Adams, J. C.** and **Hamblen, D. L.** *Outline of fractures*. London, Churchill Livingstone, 1992.

15 **Schenk, R.K.** Cytodynamics and histodynamics of primary bone repair. In: **Lane, J. M.** (ed.) *Fracture Healing.* London, Churchill Livingstone, 1987, 23-32.

16 **Sevitt, S.** *Bone repair and fracture healing in man.* London, Churchill Livingstone, 1981.

17 **Ilizarov, G. A.** The tension-stress effect on the genesis and growth of tissues. *Clin. Orthop.*, 1989, **238**, 249-281.

18 **Podolsky, A.** and **Chao, E. Y. S.** Mechanical performance of Ilizarov circular external fixators in comparison with other external fixators. *Clin. Orthop.*, 1993, **293**, 61-70.

19 **Schenk, R.K., Müller, J.** and **Willenegger, H.** Experimentell-histologischer Beitrag zur Entstehung und Behandlung von Pseudarthrosen. *Unfallheilkunde*, 1986, **94**, 15-24.

20 **Kershaw, C. J., Cunningham, J. L.** and **Kenwright, J.** Tibial external fixation, weight bearing, and fracture movement. *Clin. Orthop.*, 1993, **293**, 28-36.

21 **Goodship, A. E.** and **Kenwright, J.** The influence of induced micromovement upon the healing of experimental tibial fractures. *J. Bone Jt. Surg.*, 1985, **67B**, 650-655.

22 **Kenwright, J.** and **Goodship, A. E.** Controlled mechanical stimulation in the treatment of tibial fractures. *Clin. Orthop.*, 1989, **241**, 36-47.

23 **Noordeen, M.H.H., Lavy, C.B.D., Shergill, N.S., Tuite, J.D.** and **Jackson, A.M.** Cyclic micromovement and fracture healing. *J. Bone Jt. Surg.*, 1995, *77B, 645-648.*

24 **Matsushita, T.** and **Kurokawa, T.** Comparison of cyclic compression, cyclic distraction and rigid fixation. *Acto Orthop. Scand.* 1995, **69(1)**, 95-98.

25 **Sarmiento, A., Schaefer, J. F., Beckerman, L., Latta, L. L.** and **Enis, J. E.** Fracture healing in rat femora as affected by functional weight-bearing. *J. Bone Jt. Surg.*, 1977, **59A**, 369-375.

26 **Aro, H. T.** and **Chao, E. Y. S.** Bone-healing patterns affected by loading, fracture fragment stability, fracture type, and fracture site compression. *Clin. Orthop.*, 1993, **293**, 8-17.

27 **Sarmiento, A., McKellop, H.A., Llinas, A., Park, S.H., Lu, B., Stetson, W.** and **Rao, R.** Effect of loading and fracture motions on diaphyseal tibial fractures. *J. Orthop. Res.*, 1996, **14**, 80-84.

28 **Gardner, T.N., Evans, M., Hardy, J.** and **Kenwright, J.** Dynamic interfragmentary motion in fractures during routine patient activity. *Clin. Orthop.*, 1997, **336**, 216-225.

29 **Brooker, A. F., Cooney, W. P.** and **Chao, E.Y.** *Principles of external fixation*. Baltimore, Williams and Wilkins, 1983.

30 **Mears, D. C.** History of external fixation. In: **Brooker, A. F.** and **Edwards, C. C.** (eds) *External fixation: Current state of the art*. Baltimore, Williams and Watkins, 1979.

31 **Behrens, F.** A primer of fixator devices and configurations. *Clin. Orthop.*, 1989, **241**, 5-14.

32 **Behrens, F.** General theary and principles of external fixation. *Clin. Orthop.*, 1989, **241**, 15-23.

33 **Paley, D., Fleming, B., Catagni, M., Kristiansen, T.** and **Pope, M.** Mechanical evaluation of external fixators used in limb lengthening. *Clin. Orthop.,* 1990, **250**, 50-57.

34 **Augat, P., Merk, J., Ignatius, A., Margevicius, K., Bauer, G., Rosenbaum, D.** and **Claes, L.** Early, full weightbearing with flexible fixation delays fracture healing. *Clin. Orthop.,* 1996, **328**, 194-202.

35 **Pettilä, M.H., Sarna, S., Paavolainen, P.** and **Michelsson, J. E.** Short term external support promotes healing in semirigidly fixed fractures. *Clin. Orthop.,* 1997, **343**, 157-163.

36 **Claes, L., Augat, P., Suger, G.** and **Wilke, H.J.** Influence of size and stability of the osteotomy gap on the success of fracture healing. *J. Orthop. Res.,* 1997, **15**, 577-584.

37 **Pettine, K. A., Chao, E. Y.** and **Kelly, P. J.** Analysis of the external fixator pin-bone interface. *Clin. Orthop.,* 1993, **293**, 18-27.

38 **Cattermole, H.C., Cook, J.E., Fordham, J.N., Muckle, D.S.** and **Cunningham, J.L.** Bone mineral changes during tibial fracture healing. *Clin. Orthop.,* 1997, **339**, 190-196.

39 **Ilizarov, G. A.** *Transosseous Osteosynthesis.* Berlin, Springer Verlag, 1992.

40 **Bianchi Maiocchi, A.** and **Aronson, J.** *Operative principles of Ilizarov.* Baltimore, Williams and Wilkins, 1991.

41 **Ilizarov, G. A.** Clinical application of the tension-stress effect for limb lengthening. *Clin. Orthop.,* 1990, **250**, 8-26.

42 **Paley, D.** Problems, obstacles, and complications of limb lengthening by the Ilizarov technique. *Clin. Orthop.,* 1990, **250**, 81-104.

43 **Yasui, N., Kojimoto, H., Saski, K., Kitada, A., Shimizu, H.** and **Shimomura, Y.** Factors affecting callus distraction in limb lengthening. *Clin. Orthop.,* 1993, **293**, 55-60.

44 **Williams, M. O.** Long-term cost comparison of major limb salvage using the Ilizarov method versus amputation. *Clin. Orthop.,* 1994, **301**, 156-158.

45 **Aronson, J.** and **Harp, J. H.** Mechanical forces as predictors of healing during tibial lengthening by distraction osteogenesis. *Clin. Orthop.,* 1994, **301**, 73-79.

46 **Karaharju, E. O., Aalto, K., Kahri, A., Lindberg, L.A., Kallio, T., Karaharju-Suvanto, T., Vauhkonen, M.** and **Peltonen, J.** Distraction bone healing. *Clin. Orthop.,* 1993, **297**, 38-43.

47 **Wolfson, N., Hearn, T. C., Thomason, J. J.** and **Armstrong, P. F.** Force and stiffness changes during Ilizarov leg lengthening. *Clin. Orthop.,* 1990, **250**, 58-60.

48 **Orbay, G. L., Frankel, V. H.** and **Kummer, F. J.** The effect of wire configuration on the stability of the Ilizarov external fixator. *Clin. Orthop.,* 1992, **279**, 299-302.

49 **Nele, U., Maffulli, N.** and **Pintore, E.** Biomechanics of radiotransparent circular external fixators. *Clin. Orthop.,* 1994, **308**, 68-72.

50 **Wilkes, R.A., Harrison, A.** and **Atkins, R.M.** Assessment of mechanical stability of a parallel wire bone transport system for use with an Ilizarov frame. *Proc. Instn. Mech. Engrs.*, 1995, **209H**, 197-202.

51 **Webb, J., Herling, G., Gardener, T., Kenwright, J.** and **Simpson, A.H.R.W.** Manual assessment of fracture stiffness. *Injury,* 1996, **27(5)**, 319-320.

52 **Richardson, J.B., Cunningham, J.L., Goodship, A.E., O'Connor, B.T.** and **Kenwright, J.** Measuring stiffness can define healing of tibial fractures. *J. Bone Jt. Surg.,* 1994, **76B**, 389-394.

53 **Chehade, M.J., Pohl, A.P., Pearcy, M.J.** and **Nawana, N.** Clinical implications of stiffness and strength changes during fracture healing. *J. Bone Jt. Surg.,* 1997, **79B**, 9-12.

54 **Nicholls, P.J., Berg, E., Bliven, F.E.** and **Kling, J.M.** X-ray diagnosis of healing fractures in rabbits. *Clin. Orthop.,* 1979, **142**, 234-236.

55 **Markel, M. D.** and **Chao, E. Y.** Noninvasive monitoring techniques for quantitative description of callus mineral content and mechanical properties. *Clin. Orthop.*, 1993, **293**, 37-45.

56 **Mazess, R.B.** Noninvasive bone measurements. In: **Kunin, A.** (ed.) *Skeletal research II.* New York, Academic Press, 1983, 277.

57 **Kristiansen, B.** and **Borgwardt, A.** Fracture healing monitored with strain gauges. *Acto Orthop. Scand.* 1992, **63(2)**, 612-614.

58 **Jorgensen, T. E.** Measurements of stability of crural fractures treated with Hoffman Osteotaxis. Parts I-IV. *Acto Orthop. Scand.* 1972, **43**, 188-218 and 264-291.

59 **Evans, M., Kenwright J.** and **Cunningham, J. L.** Design and performance of a fracture monitoring transducer. *J. Biomedical Eng.* 1988, **10**, 64-69.

60 **Cunningham, J. L., Evans, M.** and **Kenwright, J.** Mechanical measurements of fracture repair. In: *The changing role of engineering in orthopaedics*, *Proceedings of the Institution of Mechanical Engineers*, 1989, 133-138.

61 **Kay, P. R., Ross, E.** and **Powell, E. S.** Development and clinical application of an external fixator monitoring system. *J. Biomedical Eng.* 1989, **11**, 240-244.

62 **Kenwright, J., Richardson, J.B., Goodship, A.E., Evans, M., Kelly, D.J., Spriggins, A.J., Newman, J.H., Burrough, S.J., Harris, J.D.** and **Rowley, D.I.** Effect of controlled axial micromovement on healing of tibial fractures. *Lancet*, 1986, ii, 1185-1187.

63 **Richardson, J. B., Kenwright, J., Cunningham, J.L., Beavis, A., Evans, M.** and **Tew, T.** Clinical applications of fracture stiffness measurements. *Annual Report of the Oxford Orthopaedic Engineering Centre*, 1987, **14**, 61-65.

64 **Ricciardi, L., Perissionotto, A.** and **Dabala, M.** Mechancical monitoring of fracture healing using ultrasound imaging. *Clin. Orthop.*, 1993, **293**, 71-76.

65 **Harp, J. H., Aronson, J.** and **Hollis, M.** Noninvasive determination of bone stiffness for distraction osteogenesis by quantitative computed tomography scans. *Clin. Orthop.*, 1994, **301**, 42-48.

66 **Cranage, R. W.** A film densiometer method of bone scan quantitation, *Br. J. Radiol.*, 1984, **57**, 831-832.

67 **Aro, H. T., Wippermann, B.W., Hodgson, S.F., Wahner, H.W., Lewallen, D.G.** and **Chao, E.Y.S.** Prediction of properties of fracture callus by measurement of mineral density using micro-bone densitometry. *J. Bone Jt. Surg.*, 1989, **71A**, 1020-1030.

68 **Mazess, R. B, Collick, B., Trempe, J., Barden, H.** and **Hanson, J.** Performance evaluation of a dual-energy x-ray densitometer. *Calcif. Tiss. Int., 1989,* ***44****, 228-232.*

69 **Pacifici, R., Rupich, R., Vered, I., Fischer, K.C., Griffin, M., Susman, N.** and **Avioli, L.V.** Dual energy radiography (DER): A preliminary comparative study. *Calcif. Tiss. Int.*, 1988, **43**, 189-191.

70 **Lowet, G., van Audekercke, R., van der Perre, G., Geusens, P., Dequeker, J.** and **Lammens, J.** The relation between resonant frequencies and torsional stiffness of long bones in-vitro. Validation of a simple beam model. *J. Biomechanics*, 1993, **26**, 689-696.

71 **Lowet, G., Dayuan, X.** and **van der Perre, G.** Study of the vibrational behaviour of a healing tibia using finite element modelling *J. Biomechanics*, 1996, **29**, 1003-1010.

72 **van der Perre, G., van Audekercke, R., Martens, M.** and **Mulier, J.C.** Identification of *in-vivo* vibration modes of human tibiae by modal analysis. *J. Biomech. Eng.*, 1983, **105**, 244-248.

73 **Fellinger, M., Schanner, A., Szyszkowitz, R. Leitgeb, N., Stockenhuber, N.** and **Roupec, R.** Computerisierte Sonometrie - die Anwendung eines nicht-invasiven Verfahrens zur Stabilitätsbeurteilung nach Frakturen. *Akt. Traumatol.*, 1993, **23**, 235-238.

74 **Lowet, G.** and **van der Perre, G.** Ultrasound velocity measurement in long bones: Measurement method and simulation of ultrasound wave propagation. *J. Biomechanics*, 1996, **29**, 1255-1262.

75 **Cunningham, J. L., Evans, M.** and **Harris, J. D.** The measurement of stiffness of fractures treated with external fixation. *Proc. Instn. Mech. Engrs.*, 1987, **16H**, 229-232.

76 **Cunningham J. L., Kenwright, J.** and **Kershaw, C. J.** Biomechanical Measurement of fracture healing. *Med. Eng. & Tech.*, 1990, **14**, 92-101.

77 **Beaupre, G. S., Hayes, W. C., Jofe, M. H.** and **White, A. A.** Monitoring fracture site properties with external fixation. *J. Biomech. Eng.*, 1983, **105**, 120-126.

78 **Nishimura, N.** Serial strain gauge measurement of bone healing in Hoffman external fixation. *Orthopaedics*, 1984, **7**, 677-684.

79 **Laval-Jeantet, A.M., Roger, B., Bouysse, S., Bergot, C.** and **Mazess, R.B.** Influence of vertebral fat content on quantitative CT density. *Radiology*, 1986, **159**, 463-466.

80 **Wu, J.J., Shyr, H.S., Chao, E.Y.S.** and **Kelly, P.J.** Comparison of osteotomy healing under external fixation devices with different stiffness characteristics. *J. Bone Jt. Surg.*, 1984, **66A**, 1258-1264.

81 **Churches, A.E.** and **Howlett, C.R.** The response of mature cortical bone to controlled time varying loading. In: **Cowin, S.C.** (ed.) *Mechanical properties of bone*. Chicago, Association for the study of medical education, 1981, 69-80.

82 **Kummer, F. J.** Biomechanics of the Ilizarov external fixator. *Clin. Orthop.*, 1992, **280**, 11-14.

83 **Paley, D.** Biomechanics of the Ilizarov external fixator. In: **Bianchi Maiocchi, A.** and **Aronson, J.** (eds.) *Operative principles of Ilizarov*. Baltimore, Williams and Wilkins, 1991, 33-41.

84 **Gasser, B., Boman, B., Wyder, D.** and **Schneider, E.** Stiffness characteristics of the circular Ilizarov device as opposed to conventional external fixators. *J. Biomech. Eng.,* 1990, **112**, 15-20.

85 **Schneider, E., Sasse, S., Schmidt, H. G. K.** and **Schümann, U.** Zur Biomechanik des Ringfixatuers - Beiträge einzelner Strukturelemente. *Unfallchirurg*, 1992, **95**, 580-587.

86 **Bronson, D.G., Samchukov, M.L., Birch, J.G., Browne, R.H.** and **Ashmen, R.B.** Stability of external circular fixation: a multi-variable biomechanical analysis. *Clin. Biomech.*, 1998, **13**, 441-448.

87 **Calhoun, J. H., Li, F., Ledbetter, B. R.** and **Gill, C. A.** Biomechanics of the Ilizarov fixator for fracture fixation. *Clin. Orthop.,* 1992, **280**, 15-21.

88 **Fleming, B., Paley, D., Kristiansen, T.** and **Pope, M.** A biomechanical analysis of the Ilizarov external fixator. *Clin. Orthop.,* 1989, **241**, 95-105.

89 **Delprete, C.** and **Gola, M. M.** Mechanical performance of external fixators with wires for the treatment of bone fractures - Part 1: Load-displacement behaviour. *J. Biomech. Eng.,* 1993, **115**, 29-36.

90 **Delprete, C.** and **Gola, M. M.** Mechanical performance of external fixators with wires for the treatment of bone fractures - Part 2: Wire tension and slippage. *J. Biomech. Eng.,* 1993, **115**, 37-42.

91 *1993 Annual book of ASTM standards: Section 13 Medical devices and services*. Philadelphia, ASTM, 1993, 22-24.

92 **Moorcroft C.I., Ogrodnik, P.J., Thomas, P.B.M.** and **Verborg, S.** A data-logging system to monitor bone fracture movement contiuously. *Med. Eng. Phys.* 1997, **19**, 286-290.

93 **Simpson, A.H.R.W., Cunningham, J.L.** and **Kenwright, J.** The forces which develop in the tissues during leg lengthening. *J. Bone Jt. Surg.,* 1996, **78B**, 979-983.

94 **Gardner, T.N., Evans, M., Simpson, A.H.R.W., Kyberd, P.J.** and **Kenwright, J.** A method of examining the magnitude and origin of "soft"

and "hard" tissue forces resisting limb lengthening. *Med. Eng. Phys.* 1997, **19**, 405-411.

95 **Calhoun, J.H, Li, F., Bauford, W.L., Lehman, T., Ledbetter, B.R.** and **Lowery, R.** Rigidity of half-pins for the Ilizarov external fixator. *Bull. Hosp. Jt. Diseases*, 1992, **52**, 21-26.

96 **Caja, V.L., Kim, W., Larsson, S.** and **Chao, E.Y.S.** Comparison of the mechanical performance of three types of external fixators: linear, circular and hybrid. *Clin. Biomech.*, 1995, **8**, 401-406.

97 **Waanders, N. A., Lawton, J.N., Steen, H., Goulet, J.A.** and **Goldstein, S.A.** Clinical estimation of Ilizarov fixator axial stiffness based on wire and half pin contributions. *Bull. Hosp. Jt. Diseases*, 1993-1995, **53**, 10-13.

98 **Keller, T.S.** Predicting the compressive mechanical behaviour of bone. *J. Biomechanics*, 1994, **27**, 1159-1168.

99 **Evans, F.G.** *Mechanical properties of bone*. Springfield, Thomas, 1973.

100 **Finlay, J.B., Harada, I, Bourne, R.B., Rorabeck, C.H., Hardie, R.** and **Scott, M.A.** Analysis of the pull-out strength of screws and pegs used to secure tibial components following total knee arthroplasty. *Clin. Orthop.*, 1989, **247**, 220-231.

101 **Bourgois, R.** and **Burny, F.** Feasibility of bone healing measurement with external fixation. *Orthopaedics*, 1984, **7**, 673-676.

102 **Kai-Nan, A., Kasmin, R. A.** and **Chao, Y.S**. Theoretical analysis of fracture healing monitoring with external fixators. *Proc. Instn. Mech. Engrs.*, 1988, **17H**, 11-15.

103 **Nishimura, N.** and **Yamana Y.** Strain gauge assessment in various external fixations. *3rd World Congress on Biomechanics*. Sapporo, Japan, 2nd - 8th August, 1998. 247.

104 **Ceffa, R.M.** and **Bombelli, M.** *Instrumentation for the extensimetric monitoring with the Ilizarov external fixator.* Novara (Italy), Azienda Ospedaliera Maggiore della Carità, no date.

105 **Bombelli, M.** Orthopaedic and Trauma Department, Azienda Ospedaliera Maggiore della Carità, Novara, Italy. *Personal communication*, 1996.

106 **Gosney, M.S.** Group Manager, Smith & Nephew Orthopaedic Trauma Divsion, Smith and Nephew Richards Inc., Mephis, TN. *Personal communication*, 1996.

107 **Hardy, J.R.W., De Jong, E.J.** and **Richardson, J.B.** Fracture Stiffness. *J.Orthopaedic Techniques*, 1994, **2**(4), 177-189.

108 **Shah, K.M., Nicol, A.C.** and **Hamblen, D.L.** Fracture stiffness measurement in tibial shaft fractures: a non-invasive method. *Clinical Biomechanics*, 1995, **10(8)**, 395-400.

109 **Prat, J., Juan, J.A., Vera, P., Hoyos, J.V., Dejoz, R., Peris, J.L., Sánchez-Lacuesta, J.** and **Comín, M.** Load transmission through the callus site with external fixation systems: Theoretical and experimental analysis. *J. Biomechanics*, 1994, **27**, 469-478.

110 **Perren, S.M.** Physical and biological aspects of fracture healing with special reference to internal fixation. *Clin. Orthop.*, 1979, **142**, 234-236.

111 **Crolet, J.M., Aoubiza, B.** and **Meunier, A.** Compact bone: Numerical simulation of mechanical characteristics. *J. Biomechanics*, 1993, **26**, 677-687.

112 **Walsh, W.R., Sherman, P., Howlett, C.R., Sonnabend, D.H.** and **Ehrlich, M.G.** Fracture healing in a rat osteopenia model. *Clin. Orthop.*, 1997, **342**, 218-227.

113 **Neubert, H.K.P.** *Strain gauges: kinds and uses.* London, Macmillan, 1967. Chapter 4.

Glossary

Anterior	At, or towards, the front of the body.
Approximate	To bring to things close together, e.g. during reduction the bone ends are approximated.
Atrophic Non-union	A non-union in which there is no evidence of cellular activity at the level of the fracture.
Callus	Material which forms around the bone ends at a fracture site. Early callus can develop into osseous material or fibrocartilage.
Compound fracture	A fracture associated with an open wound; generally the fracture site has come into contact with the outside environment and is liable to become infected.
Conventional fracture management	Generally used to describe all forms of fracture management other than external fixation.
Corticotomy	A minimally traumatic surgical division of bone with maintenance of the integrity of the periosteum.
Distraction osteogenesis	A technique for correcting segmental defects in bone; also termed bone transport, or the Ilizarov method. See section 2.5.

Diaphysis	The shaft of a long bone.
Lateral	Of, at, or towards, the side of the body.
Management	The technique of treating a disorder.
Medial	Situated towards the midline of the body.
Non-union	The failure of a fracture to form new bone and to regain bony continuity.
Osteotomy	A surgical division of bone.
Posterior	At, or towards, the back of the body.
Reduction	The restoration of the bone fragments to their pre-fracture positions and alignments.
Resection	Surgical removal of diseased or damaged tissue.
Trauma Residual	A fracture of traumatic origin which has failed to unite during a previous regime of management.

Appendix I - Patient Case Histories

Patient T1

Age	28
Sex	Male
Duration of Healing	16 Weeks
Past Medical History	Nothing significant.

Mode of Injury:

Patient originally had a severe 3B compound fracture of the right tibia. One week after frame removal the fracture re-fractured with minimal trauma; re-fracture occurred whist the patient was putting a sock on his right foot.

Description of fracture:

Insufficiency fracture.

Other Injuries:

Not significant.

Frame Configuration:

6 x 180 mm carbon fibre rings. Fixation by 2 olive wires and one 6 mm half pin to the distal ring, one olive wire and one 6 mm pin to the proximal ring, and 2 x 6 mm pins to the other rings. 4 connecting rods.

Chronology:

Week	
-2	Re-fracture occurs.
0	Frame re-applied.
8	Radiographs showed excellent alignment and callus formation.
16	Fracture was judged clinically united; bone remodelling had begun.
17	Frame removed.

Patient T2

Age	23
Sex	Female
Duration of Healing	45 Weeks

Past Medical History:

Transverse fracture of the midshaft of the left tibia five years previously, about 5 cm above the current fracture line. Fracture united with non-operative management.

Mode of Injury:

Fell off horse which then trampled on her left leg.

Description of fracture:

Highly displaced oblique fracture of the left tibia just distal to mid shaft.

Other Injuries:

Severe damage to the soft tissues at the fracture site.

Frame Configuration:

4 x 160 mm carbon fibre rings. Fixation by 3 olive wires to the distal ring and 2 x 5 mm pins, in a delta formation, to each of the other rings. 4 connecting rods.

Chronology:

Week	
-71	The fracture was nailed with a Biomet intramedullary nail which was locked distally and not proximally.
-3	Radiographs show little or no sign of progress towards union over the past 16 months. Hypertrophic non-union. 1 cm shortening.
-1	Intramedullary nail removed
0	1 cm fibulotomy performed at the junction of the proximal and middle thirds of the fibula. Frame applied.
2	Radiographically the non-union site showed progress towards union. Distraction was initiated at 0.75 mm per day.

6	Evidence on the lateral view radiograph that there was some devitalised bone in the site of the fracture. Non-union site had distracted approximately 6 mm.
8	Distractate was now out to length. Bone appeared to be forming in the distractate.
12	One of the olive wires required re-tensioning. Radiographic evidence of new bone formation.
22	New bone was forming, albeit rather slowly.
26	Radiographically the fracture was uniting.
30	Radiographically the bone was slowly uniting and forming callus, particularly in a lateral buttress.
36	Good progress to union, particularly with the callus on the lateral side of the fracture.
45	Fracture united. Frame de-stabilised.
52	Frame removed.

Patient T3

Age	37
Sex	Male
Duration of Healing	12 Weeks

Past Medical History

On alcohol rehabilitation programme.

Mode of Injury:

Road traffic accident, pedestrian struck by car.

Description of fracture:

Closed oblique fracture of the right proximal tibia.

Other Injuries:

Not significant.

Frame Configuration:

4 x 180 mm carbon fibre rings, 2 wires per ring. 4 connecting rods.

Chronology:

Week	
0	Frame applied.
1	Radiographs revealed excellent alignment.
2	Re-admitted for four days because of pin site infections. Given intravenous antibiotics.
10	Good callus formation. Fracture united.
12	Frame removed.

Patient T4

Age	33
Sex	Male
Duration of Healing	N/A
Past Medical History	Nothing significant.

Mode of Injury:

Road traffic accident; pedestrian hit by car.

Description of fracture:

High energy, 3B, compound, left tibial oblique fracture.

Other Injuries:

Not significant.

Frame Configuration:

4 x 180 mm rings, the two outer rings being steel and the two central rings being carbon fibre. 2 x olive wires per ring, plus an extra wire on the proximal carbon fibre ring. 4 connecting rods.

Chronology:

Week	
-40	Treated with wound debridement and an Orthofix fixator. During the course of initial debridement a 7 cm segment of fibula was resected.
-14	Fracture had developed into an normotrophic non-union.
0	Frame applied. On examination there appeared to be no definite segment of dead bone and so it was decided to unite the fracture by anatomically reducing it followed by compression.
5	Radiographically the non-union was well approximated and bone resorption was occurring
12	Radiographs showed that an atrophic non-union was developing, with bone infection and some bone death.

Patient T5

Age	48
Sex	Male
Duration of Healing	16 Weeks
Past Medical History	Nothing significant.

Mode of Injury:

Fell 10 feet from roof.

Description of fracture:

Severely comminuted type 3 pillion fracture of the right tibia. There was a large posterior fragment which included the posterolateral fragment. There was a medial fragment, an anterolateral fragment, some comminution anteromedially and a dye stamp fragment. There was very significant displacement anteriorly.

Other Injuries:

Not significant.

Frame Configuration:

3 x 160 mm carbon fibre rings. Fixation by 2 olive wires distally and two 5 mm pins on each of the other rings. 4 connecting rods.

Chronology:

Week	
-2	Bone fragments manipulated into position and stabilised with back slab.
0	Fracture reduced using an AO distractor and then a frame applied. Non-weight bearing for six weeks.
12	Signs that fracture was uniting in radiographs. A significant amount of callus was visible around the metaphysis.
16	Clinically and radiographically united.
20	Frame removed

Patient T6

Age	29
Sex	Male
Duration of Healing	N/A

Past Medical History

Thirteen years previously had a severe compound fracture of the left tibia with vascular injury and soft tissue loss. This was treated with a latissimus dorsi transfer graft to cover the bone. Eventually the fracture united and apart from skin scarring the leg was fully functional.

Mode of Injury:

Tripped on a grass bank and the tibia re-fractured.

Description of fracture:

Open transverse fracture of left tibia.

Other Injuries:

Not significant.

Frame Configuration:

4 x 200 mm carbon fibre rings, proximal ring was 5/8 ring. Fixation by two olive wires in the proximal ring and 2 x 6 mm pins on other rings. 5 connecting rods.

Chronology:

Week	
-2	Fracture temporarily reduced and immobilised by an above knee cast.
0	35 mm of bone resected in order to provide viable bone ends and frame applied.
1	Further necrotic tissue debrided.
7	Radiographs showed very satisfactory callus in the posterolateral aspect of the fracture but a gap on the medial side.

15	Callus in the posterolateral aspect of the fracture had bridged the fracture gap.
31	Radiographs showed an excellent buttress of new bone in the posterior-lateral quadrant but no callus in the other quadrants. There was still a clearly visible fracture gap.

Patient T7

Age	40
Sex	Male
Duration of Healing	22 Weeks
Past Medical History	Nothing significant.

Mode of Injury:

Injured playing football.

Description of fracture:

Closed transverse fracture of the midshaft of the right tibia with a comminuted fracture of the fibula.

Other Injuries:

Not significant.

Frame Configuration:

4 x 160 mm carbon fibre rings. Fixation was by 2 olive wires to each of the two distal rings and the proximal ring, and 2 x 5 mm pins to the other ring. 5 connecting rods.

Chronology:

Week	
-34	Fracture treated by reamed intramedullary nailing.
-6	Radiographs show that the fibula had united but the tibia had gone to non-union. There was an abscess at the site of the non-union.
0	2 cm fibulotomy performed and frame applied. Fully weight bearing.
11	Radiographs showed that the non-union had not yet united but was uniting.
22	Fracture judged clinically united.

Patient T8

Age	49
Sex	Male
Duration of Healing	13 Weeks
Past Medical History	Nothing significant

Mode of Injury:

Pedestrian hit by sports car travelling at approximately 40 mph.

Description of fracture:

Compound grade 3B extraarticular pillon fracture of the left distal tibia.

Other Injuries:

Not significant.

Frame Configuration:

5 x 180 mm carbon fibre rings. Fixation by 2 olive wires to proximal ring, 3 olive wires to distal ring, and 2 x 5 mm pins to each of the other rings. 6 connecting rods.

Chronology:

Week	
-12	Fracture was debrided, aligned and stabilised using an Orthofix fixator with T attachment. Split skin graft was applied.
-4	Orthofix removed because pins had loosened and the orthofix was providing no support. The fracture was temporarily immobilised with a below knee cast.
0	10 mm of bone resected and frame applied.
3	Radiographs showed good alignment and early callus formation
13	Radiographs showed that the fracture is now united.

Patient T9

Age	32
Sex	Male
Duration of Healing	20 Weeks
Past Medical History	Nothing significant.

Mode of Injury:

Full beer barrel fell on right leg.

Description of fracture:

Grade 3B segmental fracture of the distal tibia.

Other Injuries:

Not significant.

Frame Configuration:

3x 160 mm carbon fibre rings. Fixation by 3 olive wires on the distal ring and 2 x 5 mm pins on the other 2 rings. 5 connecting rods.

Chronology:

Week	
-3	Fracture reduced, debrided and stabilised with an Orthofix fixator.
0	Frame applied.
9	Radiographs showed start of union.
20	Fracture judged clinically united.

Patient F1

Age	25
Sex	Male
Duration of Healing	16 Weeks
Past Medical History	Not significant

Mode of Injury:

Road traffic accident on motorcycle which collided with lamppost at 60 mph.

Description of fracture:

Open left femoral supracondylar fracture, mid distal third.

Other Injuries:

Closed comminuted right femoral shaft fracture. Traumatic amputation through middle phalanx left little finger. Intraarticular Smith's type fracture left wrist. Significant wound and de-gloving injury over right tibia.

Frame Configuration:

2 x 220 mm carbon fibre rings. 1 reference wire and two olive wires distally, 2 pins proximally. Italian arc applied proximally with two further pins. 6 connecting rods.

Chronology:

Week	
-4	4 pin, 2 bar AO fixator applied bridging the knee joint applied to stabilise the injury.
0	AO fixator removed and Ilizarov frame applied
1	Mobilisation begun with minimal weigh-bearing.
5	Radiographs showed excellent alignment.
12	Radiographs showed fracture uniting.
16	Fracture judged united from radiographic evidence.
18	Frame removed.

Appendix II - List of the Author's Publications

1. **Harrison, A.J., Hillard, P.J., Kelly, A.J., Winson, I.G.** and **Atkins, R.M.** A Method for Standardising Data Acquired with the Musgrave Footprint ® System: British Orthopaedic Foot Surgery Society Meeting, Glasgow, 9th & 10th November, 1995; *Journal of Bone and Joint Surgery*, Vol. 78(B), Supp. I, pp. 75-76. *ISSN 0301-620X*

2. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** A Comparison of the Mechanical Characteristics of Wire-Type and Half pin-Type Ilizarov Frames: British Orthopaedic Research Society Spring Meeting, Oswestry, 28th & 29th March, 1996.

3. **Harrison, A.J.** and **Hillard P.J.** A Technique for Standardising Dynamic Foot Pressure Data: *In-Vivo* Pressure Measurement Meeting, Manchester Metropolitan University, 3rd & 4th April, 1996.

4. **Harrison, A.J., Hillard, P.J., Kelly, A.J., Winson, I.G.** and **Atkins, R.M.** Standardising Data Acquired with the Musgrave Footplate System: British Orthopaedic Association Spring Meeting, Llandudno, 16th & 17th April, 1996.

5. **Hillard, P.J.** Finite Element Analysis of Ilizarov Frames: Circular Frame Users Group Meeting, Bristol, 22nd April, 1996.

6. **Kelly, A.J., Hillard, P.J., Harrison, A.J., Winson, I.G.** and **Atkins, R.M.** Walkway Length in Dynamic Foot Pressure Measurement: 2nd Congress of the European Federation of National Foot and Ankle Societies, Basel, 2nd - 4th May, 1996; *Journal of Bone and Joint Surgery*, Vol. 79(B), Supp. IV, p. 436. *ISSN 0301-620X*

7. **Kelly, A.J., Hillard, P.J., Harrison, A.J., Winson, I.G.** and **Atkins, R.M.** A New Method for Standardising Data Acquired with the Musgrave Footplate System: 20th World Congress of the Société Internationale de Chirurgie Orthopédique et de Traumatologie, Amsterdam, 21st - 23rd August, 1996.

8. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** The Behaviour of Load-Bearing Wires in the Ilizarov Frame: 10th Conference of the European Society of Biomechanics, Leuven, 28th - 31st August, 1996. p.357. *ISBN 90-803242-1-3*

9. **Allen, P.E., Kelly, A.J., Hillard, P.J., Winson, I.G.** and **Atkins, R.M.** Plantar Pressure Profiles and Outcome Following Non-Operatively Treated Calcaneal Fractures: British Orthopaedic Foot Surgery Society Meeting, Newcastle-upon-Tyne, 7th & 8th November, 1996; *Journal of Bone and Joint Surgery*, Vol. 79(B), Supp. IV, p. 434. *ISSN 0301-620X*

10. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** An Automated Method for Processing Foot Pressure Data: British Orthopaedic Research Society Spring Meeting, Sheffield, 3rd & 4th March, 1997; *Journal of Bone and Joint Surgery*, Vol. 79(B), Supp. IV, p. 464. *ISSN 0301-620X*

11. **Harrison, A.J.** and **Hillard, P.J.** Foot Pressure Analysis: An Assessment of Frequently Cited Parameters; 4th Meeting of the Foot Pressure Interest Group, Stoke-on-Trent, 24th & 25th May, 1997.

12. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** Measurement of the Axial Stiffness of Fractures and Regenerate with a Circular External Frame *In-Situ*; 9th International Conference on Biomedical Engineering, Singapore, 3rd to 6th December, 1997. *ISBN 9971-88-598-0*, pp.185-187.

13. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** Automated Processing of Plantar Pressure Data; 9th International Conference on Biomedical Engineering, Singapore, 3rd to 6th December, 1997. *ISBN 9971-88-598-0,* pp. 680-681.

14. **Hillard, P.J., Harrison, A.J.** and **Atkins, R.M.** The Yielding of Tensioned Fine Wires in the Ilizarov Frame. *Proc. Instn. Mech. Engrs.*, 1998, Vol 212 Part H, pp. 37-47. *ISSN 0954-4119*

15. **Harrison, A.J.** and **Hillard, P.J.** A moment based technique for the automatic spatial alignment of plantar pressure data. *Proc. Instn. Mech. Engrs. Part H, In Press.*

Grant obtained by the author:

Atkins, R.M., Harrison, A.J. and **Hillard, P.J.** The measurement of fracture and regenerate stability within bone under conditions of circular external fixation. *South West Regional Health Authority, Research and Development Directorate.* 1996 - 1999.

Appendix III - Copy of Publication 14.

APPENDIX NOT COPIED

ON INSTRUCTION FROM

UNIVERSITY